

The information in this prospectus may change. We may not complete the exchange offer and issue the securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION

DATED MARCH 25, 2016



OFFER TO EXCHANGE SERIES B WARRANTS FOR SERIES A WARRANTS

**THE EXCHANGE OFFER WILL EXPIRE AT MIDNIGHT, EASTERN TIME,
ON APRIL 21, 2016, UNLESS EXTENDED
(SUCH DATE AND TIME, AS THE SAME MAY BE EXTENDED, THE "EXPIRATION DATE").**

We are offering to exchange Series B Warrants (the "Series B Warrants") to purchase shares of our common stock, par value \$0.01 per share (the "Warrant Shares"), for up to an aggregate of 3,157,186 outstanding Series A Warrants (the "Series A Warrants"). See "General Terms of the Exchange Offer" and "Description of Series B Warrants Included in the Exchange Offer." Each Series A Warrant can be exercised for one share of common stock at \$4.95 per share or on a cashless basis for a variable number of shares, with the ratio depending in part on the market value of our common stock. On March 16, 2016, each Series A Warrant could be exercised on a cashless basis for 10.06 shares of common stock.

For each outstanding Series A Warrant tendered by holders, we will issue 10.2 Series B Warrants, which are subject to cashless exercise at a fixed rate of one share of common stock per Series B Warrant (subject to further adjustment for stock splits, etc.). We are making this Exchange Offer upon the terms and subject to the conditions described in this prospectus and in the related Letter of Transmittal (which together, as they may be amended from time to time, constitute the "Exchange Offer").

Our common stock is listed on The NASDAQ Capital Market under the symbol "SKLN." The last reported per share price for our common stock was \$0.21, as quoted on The NASDAQ Capital Market on March 16, 2016.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 25 OF THIS PROSPECTUS FOR A DISCUSSION OF INFORMATION THAT SHOULD BE CONSIDERED IN CONNECTION WITH AN INVESTMENT IN THE SECURITIES DESCRIBED IN THIS PROSPECTUS.

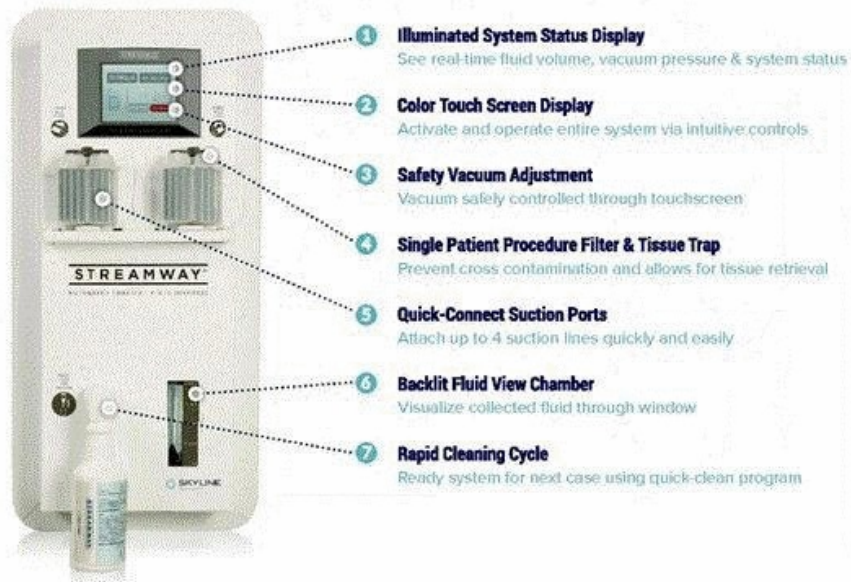
NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF OUR COMMON STOCK OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The Dealer Manager for the Exchange Offer is:

SOURCE CAPITAL GROUP, INC.

The date of this prospectus is _____, 2016.





Skyline Medical Inc. STREAMWAY® System Fluid Management System

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You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. Neither we nor the Dealer Manager have authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. Neither we nor the Dealer Manager take any responsibility for, or can provide any assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. Neither we nor the Dealer Manager are making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: Neither we nor the Dealer Manager have done anything that would permit the Exchange Offer or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

IMPORTANT INFORMATION

Series A Warrants tendered and not validly withdrawn prior to the Expiration Date may not be withdrawn at any time after the Expiration Date.

Series A Warrants to be tendered, completed and dated Letters of Transmittal and any other required documents, should be directed to Corporate Stock Transfer, Inc., who is acting as the Depository and Exchange Agent for the Exchange Offer (the "Exchange Agent"). Any requests for assistance in connection with the Exchange Offer or for additional copies of this prospectus or related materials should be directed to the Exchange Agent. Contact information for the Exchange Agent is set forth under "Depository and Exchange Agent." We and our Board have not made any recommendation as to whether or not holders should tender their Series A Warrants pursuant to the Exchange Offer.

Subject to the terms and conditions set forth in the Exchange Offer, the consideration to which an exercising holder of Series A Warrants is entitled pursuant to the Exchange Offer will be paid on the settlement date (the "Settlement Date"), which is the date promptly following the expiration date of the Exchange Offer, subject to satisfaction or waiver (to the extent permitted) of all conditions precedent to the Exchange Offer.

Notwithstanding any other provision of the Exchange Offer, our obligation to issue a Series B Warrant for any Series A Warrant validly tendered and not validly withdrawn pursuant to the Exchange Offer is subject to, and conditioned upon, the satisfaction or waiver of the conditions described herein.

Subject to applicable securities laws and the terms of the Exchange Offer, we reserve the right:

- to waive any and all conditions to the Exchange Offer that may be waived by us;
- to extend the Exchange Offer;
- to terminate the Exchange Offer; or
- to otherwise amend the Exchange Offer in any respect in compliance with applicable securities laws and stock exchange rules.

If the Exchange Offer is withdrawn or otherwise not completed, the consideration (the issuance of the Series B Warrants) will not be made to holders of Series A Warrants who have validly tendered their Series A Warrants pursuant to the terms of the Exchange Offer, and the Series A Warrants validly tendered pursuant to the terms of the Exchange Offer will be promptly returned to the tendering holders.

Only registered holders of Series A Warrants are entitled to tender their Series A Warrants in the Exchange Offer. Beneficial owners of Series A Warrants that are held of record by a broker, bank or other nominee or custodian must instruct such nominee or custodian to tender their Series A Warrants in the Exchange Offer on the beneficial owner's behalf. A letter of instruction is included in the materials provided along with this prospectus, which may be used by a beneficial owner in this process to affect the tender of Series A Warrants pursuant to the terms of the Exchange Offer. Holders who tender their Series A Warrants will not be obligated to pay brokerage fees or commissions to the Exchange Agent or us. We will pay the Dealer Manager, the Information Agent and the Exchange Agent reasonable and customary fees for their services and reimburse them for their related reasonable out-of-pocket expenses. If a broker, bank or other nominee or custodian tenders Series A Warrants on behalf of a holder, such broker, bank or other nominee or custodian may charge a fee for doing so. Holders who own Series A Warrants through a broker, bank or other nominee or custodian should consult their broker, bank or other nominee or custodian to determine whether any charges will apply.

MARKET AND INDUSTRY DATA

In this prospectus, we rely on and refer to information and statistics regarding our industry. Where possible, we obtained this information and these statistics from third party sources, such as independent industry publications, government publications or reports by market research firms, including company research, trade interviews, and public filings with the SEC. Additionally, we have supplemented third party information where necessary with management estimates based on our review of internal surveys, information from our customers and vendors, trade and business organizations and other contacts in markets in which we operate, and our management's knowledge and experience. However, these estimates are subject to change and are uncertain due to limits on the availability and reliability of primary sources of information and the voluntary nature of the data gathering process. As a result, you should be aware that industry data included in this prospectus, and estimates and beliefs based on that data, may not be reliable.

QUESTIONS AND ANSWERS ABOUT THE EXCHANGE OFFER

The following are some questions and answers regarding the Exchange Offer. It does not contain all of the information that may be important to you. You should carefully read this prospectus to fully understand the terms of the Exchange Offer, as well as the other considerations that are important to you in making your investment decision. You should pay special attention to the information provided under the captions entitled "Risk Factors" and "Special Note Regarding Forward-Looking Statements."

Who is making the Exchange Offer?

Skyline Medical Inc. (the "Company," "Skyline," "us," "we," or "our"), a Delaware corporation and the issuer of the Series A Warrants, is making the Exchange Offer. The mailing address of our principal executive offices is 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. Our telephone number at these offices is (651) 389-4800. Our common stock is currently listed on The NASDAQ Capital Market under the symbol "SKLN." See "General Terms of the Exchange Offer."

What securities are subject to the Exchange Offer?

We are offering to exchange Series B Warrants for the outstanding Series A Warrants tendered by holders on or prior to the Expiration Date, upon the terms and subject to the conditions described in this prospectus and the related Letter of Transmittal and as permitted under the terms of the Exchange Offer and the related Letter of Transmittal. Subject to the satisfaction or waiver of all conditions to the Exchange Offer, Series A Warrants that are validly tendered and not validly withdrawn will be accepted for exchange in accordance with the terms of the Exchange Offer. Our acceptance of the tendered Series A Warrants for exchange and the closing of the Exchange Offer is subject to the conditions described under "General Terms of the Exchange Offer — Conditions of the Exchange Offer."

The Series B Warrants and the Warrant Shares will be registered pursuant to this registration statement at the time the Series B Warrants are issued. See "Description of Series B Warrants Included in the Exchange Offer."

Why are we making the Exchange Offer?

We believe that the variable number of shares currently issuable upon a cashless exercise of Series A Warrants creates significant market uncertainty and downward pressure on the market value of our common stock. The purpose of the Exchange Offer is to replace as many Series A Warrants as possible with Series B Warrants, which feature a fixed number of shares issuable upon a cashless exercise. We believe this exchange will create more certainty and transparency in the market for our common stock and our capital structure, which we believe will benefit our stockholders. See "General Terms of the Exchange Offer."

What securities will I receive in the Exchange Offer, and how do they compare with the terms of my existing securities?

If you validly tender your Series A Warrants pursuant to the Exchange Offer, then, subject to the terms and conditions of the Exchange Offer, for each outstanding Series A Warrant tendered, you will receive 10.2 Series B Warrants, which are subject to cashless exercise at a fixed ratio of one share of common stock per Series B Warrant (subject to further adjustment for stock splits, etc.). The Series A Warrants, in contrast, are currently each subject to a variable cashless exercise ratio that (1) increases as the market price of the stock decreases, subject to a market price floor of \$0.43 per share, and (2) fluctuates to a lesser degree based on the US Treasury rate included in the formula. From March 3, 2016 through March 16, 2016, the market value of the common stock has been less than \$0.43, and the cashless exercise ratio has ranged from 9.94 shares to 10.06 shares per Series A Warrant. On March 16, 2016 the ratio was 10.06 shares per Series A Warrant. Therefore, the 10.2 Series B Warrants to be received by a tendering holder for each Series A Warrant would currently be exercisable into a fixed number of shares that exceeds the current number of shares issuable upon a cashless exercise of the Series A Warrants being tendered.

Because the cashless exercise formula for the Series A Warrants also fluctuates based on the riskless US Treasury rate for the remaining term of the Series A Warrants, we estimate that if the applicable US Treasury rate increased to a level exceeding 5%, the ratio for the cashless exercise of the Series A Warrants could be greater than 10.2 shares of common stock per Series A Warrant. For example, we estimate that an applicable US Treasury rate of 6% would have resulted in a cashless exercise ratio of 10.22 shares of common stock per Series A Warrant.

See “General Terms of the Exchange Offer” and “Description of Series B Warrants Included in the Exchange Offer.” The Exchange Offer is subject to the conditions described under “General Terms of the Exchange Offer — Conditions of the Exchange Offer.”

When are the Series B Warrants exercisable into shares of common stock of the Company?

The Series B Warrants will be exercisable immediately upon issuance. Each Series B Warrant entitles the registered holder to purchase one share of our common stock upon cashless exercise. The Series B Warrants are exercisable for a period commencing on the date of issuance and ending on December 31, 2020. See “Description of Series B Warrants Included in the Exchange Offer” and “General Terms of the Exchange Offer.”

What percentage of the ownership of the Company will holders of Series A Warrants receive in the aggregate if the Exchange Offer is completed?

Assuming all outstanding Series A Warrants are tendered, then such holders of Series A Warrants will receive an aggregate of 32,203,297 Series B Warrants. If all of such Series B Warrants were fully exercised, such Warrant Shares would represent, in the aggregate, approximately 39% of our common stock, based on an aggregate of 82,241,077 shares outstanding.

When does the Exchange Offer expire?

The Exchange Offer will expire on the Expiration Date, which is April 21, 2016, at midnight, Eastern time, unless the Exchange Offer is extended at our sole discretion. See “General Terms of the Exchange Offer.”

Can the Exchange Offer be extended?

Yes, we can extend the Exchange Offer. See “General Terms of the Exchange Offer — Extensions, Termination or Amendment.”

Who may participate in the Exchange Offer?

All registered holders of outstanding Series A Warrants as of the date of the commencement of the Exchange Offer may participate in the Exchange Offer. The Series A Warrants that were issued to former holders of shares of our Series A Preferred Stock as a component of certain units in exchange for such shares may participate in the Exchange Offer.

What Are the Key Dates of the Exchange Offer?

| Date | Event |
|---|--|
| March 25, 2016 | Commencement of the Exchange Offer |
| April 21, 2016 (at midnight, Eastern time) | Expiration of the Exchange Offer (unless extended by us) |
| Promptly after the expiration of the Exchange Offer | Issuance of Series B Warrants |

Although we do not currently intend to do so, we may, at our discretion, extend the Exchange Offer at any time. We will have to extend the Exchange Offer if our registration statement has not been declared effective by the SEC. If we extend the Exchange Offer, we will continue to accept properly completed Letters of Transmittal and notices of withdrawal until the new expiration date. We may also cancel the Exchange Offer upon the occurrence of certain events.

Are there any conditions to the Exchange Offer?

Yes. The Exchange Offer is conditioned on the closing conditions described under “General Terms of the Exchange Offer — Conditions of the Exchange Offer.” We will not be required, but we reserve the right, to accept any Series A Warrants tendered pursuant to the Exchange Offer (or, alternatively, we may terminate the Exchange Offer) if any of the conditions of the Exchange Offer as described under “General Terms of the Exchange Offer — Conditions of the Exchange Offer” remain unsatisfied. The Exchange Offer is subject to a number of conditions with regard to events that could occur prior to the expiration of the Exchange Offer. These events include:

- no lawsuit challenging the Exchange Offer; and
- effectiveness with the SEC of our registration statement on Form S-4 of which this prospectus forms a part, and such registration statement shall not be subject to a stop order, and no proceedings for that purpose shall have been instituted or be pending or, to our knowledge, be contemplated or threatened by the SEC.

Prior to the consummation of the Exchange Offer, all conditions precedent to the closing of the Exchange Offer shall have been satisfied or waived by the holders in accordance with the terms of this prospectus and the Letters of Transmittal.

Will the new securities be freely tradable?

The Warrant Shares issuable upon exercise of the Series B Warrants received in the Exchange Offer will be freely tradable in the United States, unless you are an affiliate of the Company, as that term is defined in the Securities Act of 1933, as amended (the “Securities Act”). Our common stock is listed on The NASDAQ Capital Market under the symbol “SKLN.” Our common stock may be delisted if we fail to maintain certain market capitalization thresholds, if our common stock fails to maintain a minimum trading price of \$1.00 per share over a consecutive 30-day trading period or if we don’t continue to satisfy certain listing standards.

Prior to the Exchange Offer, there has been no public market for the Series B Warrants.

What risks should I consider in deciding whether or not to tender my Series A Warrants in exchange for the issuance of the Series B Warrants?

In deciding whether to participate in the Exchange Offer, you should carefully consider the discussion of the risks and uncertainties relating to the Exchange Offer and our Company described in the section entitled “Risk Factors,” beginning on page 25 of this prospectus.

What happens if I do not participate in the Exchange Offer?

If you currently hold Series A Warrants and do not tender them pursuant to the Exchange Offer, then, following the expiration of the Exchange Offer, your Series A Warrants will continue to be outstanding according to their terms unmodified. Among other consequences, you will continue to hold warrants that feature a fluctuating number of shares issuable upon a cashless exercise. See “General Terms of the Exchange Offer—Consequences of Failure to Participate in the Exchange Offer” and “Risk Factors.”

How do I participate in the Exchange Offer?

To tender your Series A Warrants pursuant to the terms of the Exchange Offer, you must deliver to the Exchange Agent, on or prior to the Expiration Date, such Series A Warrants and the executed, completed and dated Letter of Transmittal and other required documents. The Expiration Date is no later than midnight, Eastern time, April 21, 2016, unless extended as described in this prospectus. See “General Terms of the Exchange Offer — Extension, Termination or Amendment.”

A holder of Series A Warrants who desires to tender his, her or its Series A Warrants pursuant to the Exchange Offer and is a DTC participant should transfer their Series A Warrants electronically through DTC's automated tender offer program, subject to the terms and procedures of that system. See "General Terms of the Exchange Offer — Tender of Series A Warrants and Participation in the Exchange Offer Through DTC's Automated Tender Offer Program."

HOLDERS THAT TRANSFER THROUGH DTC NEED NOT SUBMIT A PHYSICAL LETTER OF TRANSMITTAL TO THE EXCHANGE AGENT IF SUCH HOLDERS COMPLY WITH THE TRANSMITTAL PROCEDURES OF DTC.

A holder whose Series A Warrants are held by a broker, dealer, commercial bank, trust company or other nominee must contact that nominee if that holder desires to tender its Series A Warrants and instruct that nominee to tender such Series A Warrants on the holder's behalf.

May I withdraw my tender of Series A Warrants?

Yes. You can withdraw the tender of your Series A Warrants in connection with the Exchange Offer at any time before the Expiration Date. The Expiration Date is midnight, Eastern time, on April 21, 2016, unless extended as described in the Exchange Offer documents and in this prospectus. See "General Terms of the Exchange Offer — Withdrawal of Tender and Participation in this Exchange Offer."

What happens if the tender of my Series A Warrants is not accepted in the Exchange Offer?

If we decide for any valid reason not to accept the tender of your Series A Warrants in connection with the Exchange Offer, your Series A Warrants will not be deemed to be tendered pursuant to the Exchange Offer and your Series A Warrants will remain outstanding and unmodified, subject to their current terms. See "General Terms of the Exchange Offer — Withdrawal of Tender and Participation in this Exchange Offer."

Do I need to do anything if I do not wish to tender my Series A Warrants in the Exchange Offer?

No. If you do not properly tender your Series A Warrants in connection with the Exchange Offer on or prior to the Expiration Date, then your Series A Warrants will remain outstanding and unmodified, subject to their current terms.

If I choose to tender my Series A Warrants in the Exchange Offer, do I have to tender all of my Series A Warrants in full?

No. You may tender all of your Series A Warrants in their entirety, a portion of your Series A Warrants, or none of your Series A Warrants in connection with the Exchange Offer. See "General Terms of the Exchange Offer."

How will I be taxed under U.S. federal income tax laws upon the tender of my Series A Warrants and the issuance of Series B Warrants if I am a United States holder of Series A Warrants?

We have not obtained and do not intend to obtain a ruling from the Internal Revenue Service ("IRS") regarding the U.S. federal income tax consequences of your participation in the tender of Series A Warrants in the Exchange Offer. You should consult with your own tax advisor with regard to the possibility of any federal, state, local or other tax consequences of this Exchange Offer. See "Certain U.S. Federal Income Tax Considerations."

Has the Board of Directors adopted a position on the Exchange Offer?

Our board of directors, which we refer to as the "Board of Directors" or the "Board," has approved the Exchange Offer. However, our directors do not make any recommendation as to whether you should tender your Series A Warrants and receive Series B Warrants pursuant to the Exchange Offer. You should consult your own financial, tax, legal and other advisors and must make your own decision as to whether to tender your Series A Warrants and receive Series B Warrants.

Joshua Kornberg, our President, Chief Executive Officer and Interim Chairman of the Board, holds 11,112 Series A Warrants. Mr. Kornberg intends to tender all of his Series A Warrants for Series B Warrants in the Exchange Offer. Other than Mr. Kornberg, none of our officers or directors or their respective affiliates beneficially owns any of the Exchange Units and, therefore, will not participate in the Exchange Offer.

Who will pay the fees and expenses associated with the Exchange Offer?

We will bear all of our fees and expenses incurred in connection with consummating the Exchange Offer. No brokerage commissions are payable by the holders to the Exchange Agent or us. We will pay the Dealer Manager, the Information Agent and the Exchange Agent and customary fees for their services and reimburse them for their related reasonable out-of-pocket expenses. If your Series A Warrants are held or will be held through a broker or other nominee on your behalf, your broker or other nominee may charge you a commission for doing so. You should consult with your broker or other nominee to determine whether any charges will apply. See “General Terms of the Exchange Offer.”

Who can answer questions concerning the Exchange Offer?

Requests for assistance in connection with the tender of your Series A Warrants pursuant to the Exchange Offer may be directed to the Exchange Agent for the Exchange Offer, Corporate Stock Transfer, Inc., 3200 Cherry Creek South Drive, Suite 430, Denver, CO 80209.

PROSPECTUS SUMMARY

This summary contains basic information about us and the Exchange Offer. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under "Risk Factors." Some of the statements contained in this prospectus, including statements under this summary and "Risk Factors" are forward-looking statements and may involve a number of risks and uncertainties. We note that our actual results and future events may differ significantly based upon a number of factors. You should not put undue reliance on the forward-looking statements in this document, which speak only as of the date on the cover of this prospectus.

References to "we," "our," "us," the "Company," or "Skyline" refer to Skyline Medical Inc., a Delaware corporation.

Business Overview

Skyline Medical Inc. is a medical device company manufacturing an environmentally conscientious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. We own patent rights to our products, which consist of the STREAMWAY®FMS and distribute our products to medical facilities where bodily and irrigation fluids produced during surgical procedures must be contained, measured, documented, and disposed. Our products minimize the exposure potential to the healthcare workers who handle such fluids. Our goal is to create products that dramatically reduce staff exposure without significant changes to established operative procedures, historically a major stumbling block to innovation and product introduction. In addition to simplifying the handling of these fluids, we believe our technologies provide cost savings to facilities over the aggregate costs incurred today using the traditional canister method of collection, neutralization, and disposal. We sell our products through an experienced in-house sales force. The Company has one regional manager currently on staff. We also intend to utilize independent distributors in the United States and Europe, initially, and eventually to other areas of the world.

The STREAMWAY FMS is a wall mounted fully automated system that disposes of an unlimited amount of suctioned fluid providing uninterrupted performance for surgeons while virtually eliminating healthcare workers exposure to potentially infectious fluids found in the surgical environment. The system also provides an innovative way to dispose of ascetic fluid with no evac bottles, suction canisters, transport or risk of exposure. The Company also manufactures and sells two disposable products required for system operation: a bifurcated single procedure filter with tissue trap and a single use bottle of cleaning solution. Both items are used on a single procedure basis and must be discarded after use.

Skyline's virtually hands free direct-to-drain technology (a) significantly reduce the risk of healthcare worker exposure to these infectious fluids by replacing canisters, (b) further reduces the risk of worker exposure when compared to powered canister technology that requires transport to and from the operating room, (c) reduce the cost per procedure for handling these fluids, and (d) enhance the surgical team's ability to collect data to accurately assess the patient's status during and after procedures.

Skyline believes that the STREAMWAY FMS is unique to the industry in that it allows for continuous suction to the surgical field and provides unlimited capacity to the user so no surgical procedure will ever have to be interrupted to change canisters. It is wall mounted and takes up no valuable operating room space. The FMS can replace the manual process of collecting fluids in canisters and transporting and dumping in sinks outside of the operating room that is still being used by many hospitals and surgical centers.

Skyline believes its products provide substantial cost savings and improvements in safety in facilities that still use manual processes. In cases where healthcare organizations re-use canisters, the FMS cleaning process eliminates the need for cleaning of canisters for re-use. The FMS reduces the safety issues facing operating room nurses, the cost of the handling process, and the amount of infectious waste generated when the traditional method of disposing of canisters is used. The FMS is fully automated, does not require transport to and from the operating room and eliminates any canister that requires emptying. It is positioned to penetrate its market segment due to its virtually hands free operation, simple design, ease of use, continuous suction, continuous flow, unlimited capacity and efficiency in removal of infectious waste with minimal exposure of operating room personnel to potentially infectious material.

Market—Infectious and Bio-hazardous Waste Management

There has long been recognition of the collective potential for ill effects to healthcare workers from exposure to infectious/bio-hazardous materials. Federal and state regulatory agencies have issued mandatory guidelines for the control of such materials, and in particular, bloodborne pathogens. The medical device industry has responded to this need by developing various products and technologies to limit exposure or to alert workers to potential exposure. The presence of infectious materials is most prevalent in the surgical suite and post-operative care units where often, large amounts of bodily fluids, including blood, bodily and irrigation fluids are continuously removed from the patient during the surgical procedure. Surgical teams and post-operative care personnel may be exposed to these potentially serious hazards during the procedure via direct contact of blood materials or more indirectly via splash and spray. According to the Occupational Safety and Health Administration (“OSHA”), workers in many different occupations are at risk of exposure to bloodborne pathogens, including Hepatitis B and C, and HIV/AIDS. First aid team members, housekeeping personnel, nurses and other healthcare providers are examples of workers who may be at risk of exposure.

According to the American Hospital Association’s (AHA) Hospital Statistics, 2013 edition, America’s hospitals performed approximately 86 million surgeries. This number does not include the many procedures performed at surgery centers across the country. The majority of these procedures produce potentially infectious materials that must be disposed with the lowest possible risk of cross-contamination to healthcare workers. Current standards of care allow for these fluids to be retained in canisters, located in the operating room where they can be monitored throughout the surgical procedure. Once the procedure is complete, these canisters and their contents are disposed using a variety of methods, all of which include manual handling and result in a heightened risk to healthcare workers for exposure to their contents.

We expect the hospital surgery market to continue to increase due to population growth, the aging of the population, expansion of surgical procedures to new areas, for example, use of the endoscope, which requires more fluid management, and new medical technology.

There are currently approximately 40,000 operating rooms and surgical centers in the U.S. (AHA, *Hospital Statistics*, 2008). The hospital market has typically been somewhat independent of the U.S. economy; therefore, we believe that our targeted market is not cyclical, and the demand for our products will not be heavily dependent on the state of the economy. We benefit by having our products address both the procedure market of nearly 51.6 million inpatient procedures (CDC, National Hospital Discharge Survey: 2010 table) as well as the hospital operating room market (approximately 40,000 operating rooms).

Current Techniques of Collecting Infectious Fluids

Typically, during the course of the procedure, fluids are continuously removed from the surgical site via wall suction and tubing and collected in large canisters (1,500 – 3,000 milliliters (ml) capacity or 1.5–3.0 liters) adjacent to the surgical table. These canisters, made of glass or high impact plastic, have graduated markers on them allowing the surgical team to make estimates of fluid loss in the patient both intra-operatively as well as for post-operative documentation. Fluid contents are retained in the canisters until the procedure is completed or until the canister is full and needs to be removed. During the procedure the surgical team routinely monitors fluid loss using the measurement calibrations on the canister and by comparing these fluid volumes to quantities of saline fluid introduced to provide irrigation of tissue for enhanced visualization and to prevent drying of exposed tissues. After the procedure is completed the fluids contained in the canisters are measured and a calculation of total blood loss is determined. This is done to ensure that no excess fluids of any type remain within the body cavity or that no excessive blood loss has occurred, both circumstances that may place the patient at an increased risk post-operatively.

Once total blood loss has been calculated, the healthcare personnel must dispose of the fluids. This is typically done by manually transporting the fluids from the operating room to a waste station and directly pouring the material into a sink that drains to the sanitary sewer where it is subsequently treated by the local waste management facility, a process that exposes the healthcare worker to the most risk for direct contact or splash exposure. Once emptied these canisters are placed in large, red pigmented, trash bags and disposed of as infectious waste – a process commonly referred to as “red-bagging.”

Alternatively, the canisters may be opened in the operating room and a gel-forming powder is poured into the canister, rendering the material gelatinous. These gelled canisters are then red-bagged in their entirety and removed to a bio-hazardous/infectious holding area for disposal. In larger facilities the canisters, whether pre-treated with gel or not, are often removed to large carts and transported to a separate special handling area where they are processed and prepared for disposal. Material that has been red-bagged is disposed of separately, and more expensively, from other medical and non-medical waste by companies specializing in that method of disposal.

Although all of these protection and disposal techniques are helpful, they represent a piecemeal approach to the problem of safely disposing of infectious fluids and fall short of providing adequate protection for the surgical team and other workers exposed to infectious waste. A major spill of fluid from a canister, whether by direct contact as a result of leakage or breakage, splash associated with the opening of the canister lid to add gel, while pouring liquid contents into a hopper, or during the disposal process, is cause for concern of acute exposure to human blood components—one of the most serious risks any healthcare worker faces in the performance of his or her job. Once a spill occurs, the entire area must be cleaned and disinfected and the exposed worker faces a potential of infection from bloodborne pathogens. These pathogens include, but are not limited to, Hepatitis B and C, HIV/AIDS, HPV, and other infectious agents. Given the current legal liability environment the hospital, unable to identify at-risk patients due to concerns over patient rights and confidentiality, must treat every exposure incident as a potentially infectious incident and treat the exposed employee according to a specific protocol that is both costly to the facility and stressful to the affected employee and his or her co-workers. In cases of possible exposure to communicable disease, the employee could be placed on paid administrative leave, frequently involving worker's compensation, and additional workers must be assigned to cover the affected employee's responsibilities. The facility bears the cost of both the loss of the affected worker and the replacement healthcare worker in addition to any ongoing health screening and testing of the affected worker to confirm if any disease has been contracted from the exposure incident. Canisters are the most prevalent means of collecting and disposing of infectious fluids in hospitals today. Traditional, non-powered canisters and related suction and fluid disposable products are exempt and do not require FDA clearance.

Products

The STREAMWAY Fluid Management System ("FMS")—The STREAMWAY FMS suctions surgical waste fluid from the patient using standard surgical tubing. The surgical waste fluid passes through our proprietary disposable filters and into the STREAMWAY FMS. The STREAMWAY FMS maintains continuous suction to the surgical field at all times. A simple, easy to use Human Interface Display screen guides the user through the set up process, ensuring that a safe vacuum level is identified and set by the user for each procedure and additionally guides them through the cleaning process.

In contrast to competitive products, the wall-mounted FMS does not take up any operating room floor space and it does not require the use of any external canisters or handling by operating room personnel. It does require a dedicated system in each operating room where it is to be used. The FMS is the only known direct-to-drain system that is wall-mounted and designed to collect, measure and dispose of, surgical waste. Other systems on the market are portable, meaning that they are rolled to the bedside for the surgical case and then rolled to a cleaning area, after the surgery is complete, and use canisters, which still require processing or require a secondary device (such as a docking station) to dispose of the fluid in the sanitary sewer after it has been collected. They are essentially powered canisters.

The FMS system may be installed on or in the wall during new construction or renovation or installed in a current operating room by connecting the device to the hospital's existing sanitary sewer drain and wall suction systems. With new construction or renovation, the system will be placed in the wall and the incremental costs are minimal, limited to connectors to the hospital drain and suction systems (which systems are already required in an operating room), the construction of a frame to hold the FMS in position, and minimal labor.

The Disposable Kit—The disposable kit is an integral, critical component of the FMS and our total value proposition to the customer. It consists of a proprietary, pre-measured amount of cleaning solution in a plastic bottle that attaches to the FMS. The disposal cleaning kit also includes an in-line filter with single or multiple suction ports. The proprietary cleaning solution placed in the specially designed holder is attached and recommended to be used following each surgical procedure. Due to the nature of the fluids and particles removed during surgical procedures, the FMS is recommended to be cleaned following each use. The disposables have the “razor blade business model” characteristic with an ongoing stream of revenue for every FMS unit installed, and revenues from the sale of the kits are expected to be significantly higher over time than the revenues from the sales of the unit. Our disposable, dual use filter is designed specifically for use only on our FMS. The filter is used only once per procedure followed by immediate disposal. Our operation instructions and warranty require that our filter is used for every procedure. There are no known off the shelf filters that will fit our FMS. We have developed a more effective and cost efficient filter, with intent to patent. We have exclusive distribution rights to the disposable fluid and facilitate the use of only our fluid for cleaning following procedures by incorporating a special adapter to connect the fluid to the connector on the FMS system. We will also tie the fluid usage, which we will keep track of with the FMS software, to the product warranty.

Corporate Strategy—Our strategy is focused on expansion within our core product and market segments, while utilizing a progressive approach to manufacturing and marketing to ensure maximum flexibility and profitability.

Our strategy is to:

- *Develop a complete line of wall-mounted fluid evacuation systems for use in hospital operating rooms, radiological rooms and free standing surgery centers as well as clinics and physicians’ offices.*
- *Provide products that greatly reduce healthcare worker and patient exposure to harmful materials present in infectious fluids and that contribute to an adverse working environment.*
- *Utilize existing medical products, independent distributors and manufacturer’s representatives to achieve the desired market penetration.*
- *Continue to utilize operating room consultants, builders and architects as referrals to hospitals and day surgery centers.*

Other strategies may also include:

- *Employing a lean operating structure, while utilizing the latest trends and technologies in manufacturing and marketing, to achieve both market share growth and projected profitability.*
- *Providing a leasing program and/or “pay per use” program as alternatives to purchasing.*
- *Providing service contracts to establish an additional revenue stream.*
- *Utilizing the manufacturing experience of our management team to develop sources of supply and manufacturing to reduce costs while still obtaining excellent quality. While cost is not a major consideration in the roll-out of leading edge products, we believe that being a low-cost provider will be important long term.*
- *Offering an innovative warranty program that is contingent on the exclusive use of our disposable kit to enhance the success of our after-market disposable products.*

Technology and Competition

Fluid Management for Surgical Procedures

The management of surgical waste fluids produced during and after surgery is a complex mix of materials and labor that consists of primary collection of fluid from the patient, transportation of the waste fluid within the hospital to a disposal or processing site and disposal of that waste either via incineration or in segregated landfills.

Once the procedure has ended, the canisters currently being used in many cases, and their contents must be removed from the operating room and disposed. There are several methods used for such disposal, all of which present certain risks to the operating room team, the crews who clean the rooms following the procedure and the other personnel involved in their final disposal. These methods include:

- *Direct Disposal Through the Sanitary Sewer.* In virtually all municipalities, the disposal of liquid blood may be done directly to the sanitary sewer where it is treated by the local waste management facility. This practice is approved and recommended by the EPA. In most cases these municipalities specifically request that disposed bio-materials not be treated with any known anti-bacterial agents such as glutaldehyde, as these agents not only neutralize potentially infectious agents but also work to defeat the bacterial agents employed by the waste treatment facilities themselves. Disposal through this method is fraught with potential exposure to the service workers, putting them at risk for direct contact with these potentially infectious agents through spillage of the contents or via splash when the liquid is poured into a hopper - a specially designated sink for the disposal of infectious fluids. Once the infectious fluids are disposed of into the hopper, the empty canister is sent to central processing for re-sterilization (glass and certain plastics) or for disposal with the bio-hazardous/infectious waste generated by the hospital (red-bagged).
- *Conversion to Gel for Red-Bag Disposal.* In many hospital systems the handling of this liquid waste has become a liability issue due to worker exposure incidents and in some cases has even been a point of contention during nurse contract negotiations. Industry has responded to concerns of nurses over splash and spillage contamination by developing a powder that, when added to the fluid in the canisters, produces a viscous, gel-like substance that can be handled more safely. After the case is completed and final blood loss is calculated, a port on the top of each canister is opened and the powder is poured into it. It takes several minutes for the gel to form, after which the canisters are placed on a service cart and removed to the red-bag disposal area for disposal with the other infectious waste.

There are four major drawbacks to the manual disposal process:

- It does not ensure protection for healthcare workers, as there remains the potential for splash when the top of the canister is opened.
- Based on industry pricing data, the total cost per canister increases by approximately \$2.00.
- Disposal costs to the hospital increase dramatically as shipping, handling and landfill costs are based upon weight rather than volume in most municipalities. The weight of an empty 2,500 ml canister is about 1 pound. A canister and its gelled contents weigh about 7.5 pounds, and the typical cost to dispose of medical waste is approximately \$0.30 per pound.
- The canister filled with gelled fluid must be disposed; it cannot be cleaned and re-sterilized for future use.

Despite the increased cost of using gel and the marginal improvement in healthcare worker protection it provides, several hospitals have adopted gel as their standard procedure.

Current Competition, Technology, and Costs

Single Use Canisters— In the U.S., glass reusable containers are infrequently used as their high initial cost, frequent breakage and costs of reprocessing are typically more costly than single use high impact plastic canisters, even when disposal is factored in. Each single use glass canister costs roughly \$8.00 each while the high impact plastic canisters cost \$2.00 – \$3.00 each and it is estimated that a range of two to eight canisters are used in each procedure, depending on the operation. Our FMS would replace the use of canisters and render them unnecessary, as storage and disposal would be performed automatically by the FMS. We believe our competitive advantage, however, is our unlimited capacity, eliminating the need for any high volume cases to be interrupted for canister changeover.

Solidifying Gel Powder— One significant drawback of the solidifying gels is that they increase the weight of the materials being sent to the landfill by a factor of five to seven times, resulting in a significant cost increase to the hospitals that elect to use the solidifying gels. The FMS eliminates the need for solidifying gel, providing savings in both gel powder usage and associated landfill costs.

Sterilization and Landfill Disposal—Current disposal methods include the removal of the contaminated canisters (with or without the solidifying gel) to designated biohazardous/infectious waste sites. Previously many hospitals used incineration as the primary means of disposal, but environmental concerns at the international, domestic and local level have resulted in a systematic decrease in incineration worldwide as a viable method for disposing of blood, organs or materials saturated with bodily fluids. When landfill disposal is used, canisters are included in the general red-bag disposal and, when gel is used, comprise a significant weight factor. Where hopper disposal is still in use, most of the contents of the red-bag consist only of outer packaging of supplies used in surgery and small amounts of absorbent materials impregnated with blood and other waste fluid. These, incidentally, are retained and measured at the end of the procedure to provide a more accurate assessment of fluid loss or retention. Once at the landfill site, the red-bagged material is often steam-sterilized with the remaining waste being ground up and interred into a specially segregated waste dumpsite.

Handling Costs—Once the surgical team has finished the procedures, and a blood loss estimate is calculated, the liquid waste (with or without solidifying gels) is removed from the operating room and either disposed of down the sanitary sewer or transported to an infectious waste area of the hospital for later removal. The FMS would significantly reduce the labor costs associated with the disposal of fluid or handling of contaminated canisters, as the liquid waste is automatically emptied into the sanitary sewer after measurements are obtained. We utilize the same suction tubing currently being used in the operating room, so no additional cost is incurred with our process. While each hospital handles fluid waste disposal differently, we believe that the cost of our cleaning fluid after each procedure will be less than the current procedural cost that could include the cost of canisters, labor to transport the canisters, solidifying powder, gloves, gowns, mops, goggles, shipping, and transportation, as well as any costs associated with spills that may occur due to manual handling.

A hidden but very real and considerable handling cost is the cost of infectious fluid exposure. A July 2007 research article published in *Infection Control Hospital Epidemiology* concluded that “Management of occupational exposures to blood and bodily fluids is costly; the best way to avoid these costs is by prevention of exposures.” According to the article, hospital management cost associated with occupational blood exposure can, conservatively, be more than \$4,500 per exposure. Because of privacy laws, it is difficult to obtain estimates of exposure events at individual facilities; however, in each exposure the healthcare worker must be treated as a worse case event. This puts the healthcare worker through a tremendous amount of personal trauma, and the health care facility through considerable expense and exposure to liability and litigation.

Nursing Labor—Nursing personnel spend significant time in the operating room readying canisters for use, calculating blood loss and removing or supervising the removal of the contaminated canisters after each procedure. Various estimates have been made, and our management teams estimates that that the average nursing team spends twenty minutes pre-operatively and intra-operatively setting up, monitoring fluid levels and changing canisters as needed and twenty minutes post-operatively readying blood loss estimates or disposing of canisters. Estimates for the other new technologies reviewed have noted few cost savings to nursing labor.

The FMS would save nursing time as compared to the manual process of collecting and disposing of surgical waste. Set-up is as easy as attaching the suction tube to the inflow port of the FMS. Post-operative clean-up requires approximately five minutes, the time required to dispose of the suction tubing and disposable filter to the red-bag, calculate the patient’s blood loss, attach the bottle of cleaning solution to the inlet port of the unit, initiate the cleaning cycle, and dispose of the emptied cleaning solution. The steps that our product avoids, which are typically involved with the manual disposal process include, canister setup, interpretation of an analog read out for calculating fluid, canister management during the case (i.e. swapping out full canisters), and then temporarily storing, transferring, dumping, and properly disposing of the canisters.

Marketing and Sales Distribution

We sell the FMS and procedure disposables through various methods that include a direct sales force and independent distributors covering the vast majority of major U.S. markets. Currently we have one regional manager selling, and demoing the FMS for prospective customers and distributors, as well as, supporting our current customer base for disposable resupply. We are close to signing contracts with various hospital purchasing groups and have signed on independent distributors. Our targeted customer base includes nursing administration, operating room managers, CFOs, CEOs, risk management, and infection control.

Promotion—The dangers of exposure to infectious fluid waste are well recognized in the medical community. It is our promotional strategy to effectively educate medical staff regarding the risks of contamination using current waste collection procedures and the advantages of the FMS in protecting medical personnel from inadvertent exposure. We intend to leverage this medical awareness and concern with education of regulatory agencies at the local, state and federal levels about the advantages of the FMS.

We supplement our sales efforts with a promotional mix that will include a number of printed materials, video support and a website. We believe our greatest challenge lies in reaching and educating the 1.6 million medical personnel who are exposed daily to fluid waste in the operating room or in other healthcare settings (OSHA, CPL 2-2.44C). These efforts require utilizing single page selling pieces, video educational pieces for technical education, use of scientific journal articles and a webpage featuring product information, educational materials, and training sites.

Pricing—We believe prices for the FMS and its disposable procedure kit reflect a substantial cost savings to hospitals compared to their long-term procedure costs. Our pricing strategy ensures that the customer realizes actual cost savings when using the FMS versus replacing traditional canisters, considering the actual costs of the canisters and associated costs such as biohazard processing labor and added costs of biohazard waste disposal. Our cleaning solution's bottle is completely recyclable, and the anticipated selling price of the fluid is built into our cost analysis. In contrast, an operation using traditional disposal methods will often produce multiple canisters destined for biohazard processing. Biohazard disposal costs are estimated by *Outpatient Surgery Magazine* to be 5 times more per pound to dispose of than regular waste (*Outpatient Surgery Magazine*, April 2007). Once the canister has touched blood, it is considered "red bag" biohazard waste, whereas the cleaning fluid bottle used in the FMS can be recycled or disposed with the rest of the facility's plastics.

The FMS lists for \$21,900 per system (one per operating room — installation extra) and \$24 per unit retail for the proprietary disposable kit to the U.S. hospital market. By comparison, the disposal system of Stryker Instruments, one of our competitors, retails for approximately \$25,000 plus an \$8,000 docking station and requires a disposable component with an approximate cost of \$25 per procedure and a proprietary cleaning fluid (cost unknown per procedure). Per procedure cost of the traditional disposal process includes approximate costs of \$2 – \$3.00 per liter canister, plus solidifier at \$2 per liter canister, plus the biohazard premium disposal cost approximated at \$1.80 per liter canister. In addition, the labor, gloves, gowns, goggles, and other related material handling costs are also disposal expenses.

Risks

We are subject to a number of risks, which you should be aware of before deciding to participate in the Exchange Offer. In particular, you should consider the following risks, which are discussed more fully in the section titled "Risk Factors."

- Our auditors have expressed substantial concern about our ability to continue as a "going concern."
- Our limited operating history does not afford investors a sufficient history on which to base an investment decision.
- Our business is dependent upon proprietary intellectual property rights, which if we were unable to protect, could have a material adverse effect on our business.
- If we become subject to intellectual property actions, this could hinder our ability to deliver our products and services and our business could be negatively impacted.
- We face significant competition, including competition from companies with considerably greater resources than ours, and if we are unable to compete effectively with these companies, our market share may decline and our business could be harmed.
- Our products require FDA clearance and our business will be subject to intense governmental regulation and scrutiny, both in the U.S. and abroad.
- Our product has only recently entered the commercial market and, although we anticipate market acceptance, we do not have enough customer experience with it to predict future demands.
- If our product is not accepted by our potential customers, it is unlikely that we will ever become profitable.
- We are dependent on a few key executive officers for our success. Our inability to retain those officers would impede our business plan and growth strategies, which would have a negative impact on our business and the value of an investment.
- The relative lack of public company experience of our management team may put us at a competitive disadvantage.

Corporate Information

The Company was originally incorporated on April 23, 2002 in Minnesota as BioDrain Medical, Inc. Effective August 6, 2013, the Company changed its name to Skyline Medical Inc. Pursuant to an Agreement and Plan of Merger effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly-owned subsidiary, with such Delaware corporation as the surviving corporation of the merger.

Our address is 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. Our telephone number is (651) 389-4800, and our website address is www.skylinemedical.com.

Recent Developments

Effective March 18, 2016, Richard Taney resigned as a member of the Company's Board of Directors. His resignation also created a vacancy on each of the Audit Committee and Compensation Committee of the Board. Effective March 23, 2016, the Board elected Carl Schwartz to serve as a director of the Company and appointed him to serve on the Board's Audit Committee and Compensation Committee.

THE EXCHANGE OFFER

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| The Exchange Offer | We are offering to exchange Series B Warrants for the outstanding Series A Warrants tendered by holders on or prior to the Expiration Date, upon the terms and subject to the conditions described in this prospectus and the related Letter of Transmittal and as permitted under the terms of the Exchange Offer. Subject to the satisfaction or waiver of all conditions to the Exchange Offer, Series A Warrants that are validly tendered and not validly withdrawn will be accepted for exchange in accordance with the terms of the Exchange Offer. |
| Purpose of the Exchange Offer | We believe that the variable number of shares currently issuable upon a cashless exercise of Series A Warrants creates significant market uncertainty and downward pressure on the market value of our common stock. The purpose of the Exchange Offer is to replace as many Series A Warrants as possible with Series B Warrants, which feature a fixed number of shares issuable upon a cashless exercise. We believe this exchange will create more certainty and transparency in the market for our common stock and our capital structure, which we believe will benefit our stockholders. See "General Terms of the Exchange Offer." |
| The Exchange Ratio | <p>For each outstanding Series A Warrant tendered by holders, we will issue 10.2 Series B Warrants, which are subject to cashless exercise at a fixed rate of one share of common stock per Series B Warrant (subject to further adjustment for stock splits, etc.). The Series A Warrants, in contrast, are currently each subject to cashless exercise for a variable number of shares that (1) increases as the market price of the stock decreases, subject to a market price floor of \$0.43 per share, and (2) fluctuates to a lesser degree based on the US Treasury rate included in the formula. On March 16, 2016, each Series A Warrant was subject to exercise on a cashless basis for 10.06 shares of common stock.</p> <p><u>Example:</u> On March 16, 2016, a holder of 1,000 Series A Warrants would have been entitled to receive 10,060 shares of common stock upon a cashless exercise of such Series A Warrants. If the holder accepted the Exchange Offer, the holder would receive 10,200 Series B Warrants, which in the aggregate would entitle the holder to receive 10,200 shares of common stock upon cashless exercise (subject to further adjustment for stock splits, etc.).</p> |
| Market Value of our Securities | Our Series A Warrants are not listed for trading on any market. Our shares of common stock are traded on NASDAQ under the symbol "SKLN." The last reported sale price of our shares of common stock on March 16, 2016 was \$0.21 per share. See "General Terms of the Exchange Offer—Market and Trading Information." |
| Terms of the Series B Warrants | <p>For each Series A Warrant that is exchanged, the holder will receive 10.2 Series B Warrants. Each Series B Warrant entitles the registered holder to receive upon cashless exercise one share of our common stock. The Series B Warrants have a term that expires on December 31, 2020 (compared to an expiration date of August 31, 2020 for the Series A Warrants).</p> <p>The Series B Warrants contain provisions requiring an adjustment of the number of shares of common stock issuable upon exercise in the event of stock dividends, stock splits, reorganizations, reclassifications, consolidations and the like. The Series B Warrants will be issued in book entry form.</p> |
| Expiration Date of Exchange Offer | The Exchange Offer will expire on the Expiration Date, which is at midnight, Eastern time, on April 21, 2016, unless extended by us at our sole discretion. |

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| Settlement Date | The settlement of the Exchange Offer will occur promptly after the Expiration Date. |
| Procedure for Participating in the Exchange Offer | <p>In all cases, the issuance of the Series B Warrants pursuant to the Exchange Offer will be made only after timely receipt by the Exchange Agent of the Series A Warrants, the Letter of Transmittal (or a facsimile thereof) properly completed and duly executed and any required signature guarantees and other documents required by the Letter of Transmittal.</p> <p>In lieu of physically completing and signing the Letter of Transmittal and delivering it to the Exchange Agent, DTC participants may electronically transmit their acceptance of the Exchange Offer through DTC's automated tender offer program, for which the transaction will be eligible.</p> <p>By signing or agreeing to be bound by the Letter of Transmittal and other required documents, you will represent to us that, among other things:</p> <ul style="list-style-type: none"> • any Series B Warrants that you receive will be acquired in the ordinary course of your business; • you have no arrangement or understanding with any person to participate in the distribution of the Series B Warrants; • if you are not a broker-dealer, you are not engaged in and do not intend to engage in the distribution of the Series B Warrants; and • if you are a broker-dealer, that you will receive Series B Warrants for your own account in exchange for Series A Warrants that were acquired as a result of market-making activities or other trading activities and that you will deliver a prospectus in connection with any resale of the Series B Warrants. <p>Please do not send Letters of Transmittal to us, the Dealer Manager or the Information Agent. You should send Letters of Transmittal only to the Exchange Agent, at its office as indicated under "General Terms of the Exchange Offer—Depository and Exchange Agent" in this prospectus and in the Letter of Transmittal. The Exchange Agent can answer your questions regarding how to tender your Series A Warrants.</p> |
| Procedures for Tendering Series A Warrants Through a Custodian | <p>If you are a beneficial owner of Series A Warrants, but the holder of such Series A Warrants is a custodial entity such as a bank, broker, dealer, trust company or other nominee, and you seek to tender your Series A Warrants pursuant to the Exchange Offer, you must provide appropriate instructions to such holder of the Series A Warrants in order to participate through DTC's automated tender offer program with respect to such Series A Warrants. You should keep in mind that your intermediary may require you to take action with respect to the Exchange Offer a number of days before the Expiration Date in order for such entity to tender Series A Warrants on your behalf prior to the expiration of the Exchange Offer in accordance with the terms of the Exchange Offer.</p> |
| Withdrawal of Tenders | <p>Your right to tender any Series A Warrants pursuant to the Exchange Offer will expire at the Expiration Date. You can withdraw the tender of your Series A Warrants in connection with the Exchange Offer at any time before the Expiration Date.</p> |

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| Acceptance of Series A Warrants and Delivery of Series B Warrants | We will accept any and all outstanding Series A Warrants that are properly tendered in this Exchange Offer on or before midnight, Eastern time, on the Expiration Date, if all the conditions to the completion of this Exchange Offer are satisfied or waived. We will deliver Series B Warrants to you promptly after the Expiration Date and acceptance of your Series A Warrants for Series B Warrants. Please refer to the section in this prospectus entitled “General Terms of the Exchange Offer.” |
| Return of Series A Warrants | If we do not accept any Series A Warrants tendered in the Exchange Offer for any reason described in the terms and conditions of the Exchange Offer or if any Series A Warrants tendered are withdrawn pursuant to the terms of the Exchange Offer, we will return such Series A Warrants without expense to the holder. |
| Conditions to the Exchange Offer | <p>The Exchange Offer is subject to the conditions discussed under “General Terms of the Exchange Offer — Conditions to the Exchange Offer,” including that the registration statement of which this prospectus forms a part shall have become effective under the Securities Act and not be subject to a stop order, and no proceedings for that purpose shall have been instituted or be pending or, to our knowledge, be contemplated or threatened by the SEC. We also will not be required, but we reserve the right, to waive any of the conditions to this Exchange Offer, other than the condition relating to the effectiveness of the registration statement of which this prospectus forms a part and such registration statement not being subject to a stop order or any proceedings for that purpose. We have the right, in our sole discretion, to terminate or withdraw the Exchange Offer if any of the conditions described in this prospectus are not satisfied or waived.</p> <p>See “General Terms of the Exchange Offer — Conditions to the Exchange Offer.”</p> |
| Extension; Waivers and Amendments; Termination | Subject to applicable law, we reserve the right to (1) extend the Exchange Offer; (2) waive any and all conditions to or amend the Exchange Offer in any respect (except as to the condition that the registration statement of which this prospectus forms a part having become effective under the Securities Act and such registration statement not being subject to a stop order or any proceedings for that purpose, which condition we cannot waive); or (3) terminate the Exchange Offer. Any extension, waiver, amendment or termination will be followed as promptly as practicable by a public announcement thereof, such announcement, in the case of an extension, to be issued no later than 9:00 a.m., Eastern time, on the next business day after the last previously scheduled Expiration Date. See “General Terms of the Exchange Offer— Extensions, Termination or Amendment.” |
| Differences between the Series A Warrants and the Series B Warrants | There are material differences between the terms of the Series A Warrants and the terms of the Series B Warrants, including that (1) the Series B Warrants do not permit cash exercise at a price of \$4.95 per share, (2) the Series B Warrants feature a fixed number of shares issuable upon cashless exercise and (3) the termination date of the two series of warrants differ. |
| Dealer Manager | Source Capital Group, Inc. is serving as the Dealer Manager for the Exchange Offer. |

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| Information Agent | D.F. King & Co., Inc. is serving as the Information Agent in connection with the Exchange Offer. Questions or requests for assistance, or for additional copies of the Exchange Offer documents, Letter of Transmittal or other materials should be directed to: (212) 269-5550, toll-free (866) 406-2283, or sklnu@dfking.com. |
| Depository and Exchange Agent | Corporate Stock Transfer, Inc. is serving as the Depository and Exchange Agent in connection with the Exchange Offer. Deliveries should be addressed to: Corporate Stock Transfer, Inc., 3200 Cherry Creek South Drive, Suite 430, Denver, CO 80209. |
| U.S. Federal Income Tax Considerations | We recommend that you consult with your own tax advisor with regard to the possibility of any federal, state, local or other tax consequences of the Exchange Offer. See “Certain U.S. Federal Income Tax Considerations” for a discussion of the material U.S. Federal Income Tax Consequences of participating in the Exchange Offer. |
| Registration | The Series B Warrants and the Warrant Shares will be registered pursuant to the registration statement of which this prospectus forms a part at the time the Series B Warrants are issued. See “Description of Series B Warrants Included in the Exchange Offer.” |
| Use of Proceeds | We will not receive any cash proceeds from the issuance of the Series B Warrants or from the exercise of the Series B Warrants. |
| Risk Factors | See “Risk Factors” and other information included in this Offer Letter for a discussion of factors you should consider carefully before investing pursuant to the terms of this prospectus. |
| Consequences to Holders Who Do Not Participate in the Exchange Offer | If you do not participate in this Exchange Offer, you will retain the Series A Warrants. Among other consequences, you will continue to hold warrants that feature a fluctuating number of shares issuable upon a cashless exercise. See “General Terms of the Exchange Offer—Consequences of Failure to Participate in the Exchange Offer” and “Risk Factors.” |

SUMMARY FINANCIAL DATA

The following table sets forth our summary statement of operations data for the fiscal years ended December 31, 2015 and 2014 derived from our audited financial statements and related notes included elsewhere in this prospectus. Our financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. The results indicated below are not necessarily indicative of our future performance. You should read this information together with the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

| | Year Ended December 31, | |
|---|--------------------------------|----------------|
| | 2015 | 2014 |
| Revenue | \$ 654,354 | \$ 951,559 |
| Operating Expenses: | | |
| Research and Development Expenses | 260,870 | 394,257 |
| General and Administrative Expenses | 4,793,127 | 7,024,750 |
| Total Operating Expenses | 5,053,997 | 7,419,007 |
| Loss from Operations | (4,399,643) | (6,467,448) |
| Other Income (expense): | | |
| Interest Expense | 390,887 | 377,719 |
| Gain on Equity Linked | - | (11,599) |
| Net Loss available to common shareholders | \$ (4,790,530) | \$ (6,833,568) |
| Loss per common share - basic and diluted | \$ (1.23) | \$ (2.29) |
| Weighted average number of shares - basic and diluted | 3,880,828 | 2,990,471 |
| | | |
| | As of December 31, | |
| | 2015 | 2014 |
| Balance Sheet Data: | | |
| Cash | \$ 4,856,232 | \$ 16,384 |
| Total assets | 5,632,419 | 900,977 |
| Total liabilities | 1,519,708 | 6,417,204 |
| Total shareholders' equity (deficit) | 4,112,711 | (5,516,227) |

CAPITALIZATION

The following table sets forth our capitalization, as of March 11, 2016. You should consider this table in conjunction with our financial statements and the notes to those financial statements included elsewhere in this prospectus.

| | | |
|---|----|--------------|
| Total Long-Term Liabilities | \$ | - |
| Stockholders' Equity: | | |
| Series B Convertible Preferred Stock, \$.01 par value, 10,000,000 authorized, 1,895,010 outstanding actual; 0 outstanding pro forma | | 18,950 |
| Common Stock, \$.01 par value, 100,000,000 authorized, 39,498,125 outstanding actual; 9,029,244 outstanding pro forma | | 394,981 |
| Additional paid-in capital | | 44,620,060 |
| Accumulated Deficit | | (41,778,732) |
| Total Stockholders' Equity | | 3,255,259 |
| Total Capitalization | \$ | 3,255,259 |

BACKGROUND AND PURPOSE OF THE EXCHANGE OFFER

2015 Unit Offering

On August 31, 2015, the Company completed a public offering of 1,666,667 Units (the “Units”) as described below. The public offering price in the Offering was \$9.00 per Unit, and the purchase price for the underwriter of the Offering (the “Underwriter”) was \$8.28 per Unit, resulting in an underwriting discount and commission of \$0.72 (or 8.00%) per Unit and total net proceeds to the Company before expenses of \$13.8 million. The Company had granted the Underwriter an option for a period of 45 days to purchase up to an additional 250,000 Units solely to cover over-allotments. The Underwriter chose not to purchase any additional Units under the over-allotment option. The Company paid to the Underwriter a non-accountable expense allowance equal to 1% of the gross proceeds of the Offering and agreed to reimburse expenses incurred by the Underwriter up to \$70,000. On August 31, 2015, as a result of the consummation of the Offering and the issuance of the 228,343 Exchange Units in the Unit Exchange described below, the Company issued a total of 1,895,010 Units, comprised of a total of aggregate of 1,895,010 shares of Common Stock, 1,895,010 shares of Series B Preferred Stock and 7,580,040 Series A Warrants. The underwritten public offering of Units is referred to in this prospectus as the “Unit Offering.”

Each Unit consisted of one share of common stock, par value \$0.01 per share (the “Common Stock”), one share of Series B Convertible Preferred Stock (“Series B Preferred Stock”) and four Series A Warrants. The shares of Common Stock, the shares of Series B Preferred Stock and the Series A Warrants that comprise the Units automatically separated on February 29, 2016. At that time, among other things, the Series A Warrants became exercisable on a cashless basis.

Exchange Units

In connection with the Unit Offering, the Company agreed with holders of all of its outstanding Series A Convertible Preferred Stock, par value \$0.01, with a stated value of \$100 per share (the “Series A Preferred Shares”) to exchange all of the Series A Preferred Shares for units with the same terms as the Units sold in the Unit Offering (the “Exchange Units”). In the exchange of Series A Preferred Shares for Units, for every dollar of stated value of Series A Preferred Shares tendered the holders received an equivalent value of Exchange Units based on the public offering price of the Units (the “Unit Exchange”). The Unit Exchange was consummated currently with the consummation of the Unit Offering. Upon effectiveness of the Unit Exchange, the Series A Preferred Shares were cancelled and resumed the status of authorized but unissued shares of preferred stock. On August 31, 2015, the Company consummated the Unit Exchange whereby the Company issued a total of 228,343 Exchange Units in exchange for the outstanding Series A Convertible Preferred Stock which were then cancelled. The Exchange Units were exempt from registration under the Securities Act pursuant to Section 3(a)(9) thereof. As part of the Unit Exchange, 250 shares of Series A Convertible Stock held by Joshua Komberg, the Company’s President, Chief Executive Officer and Interim Chairman of the Board, were exchanged for 2,778 Exchange Units.

The shares of Common Stock, the shares of Series B Preferred Stock and the Series A Warrants that comprised the Exchange Units automatically separated on February 29, 2016.

Unit Exchange Offer

In January 2016, we commenced a registered offer (the “Unit Exchange Offer”) to exchange, on a one-for-one basis, new units in exchange for the 1,895,010 outstanding Units that were issued in the public Unit Offering and the Unit Exchange. Each new unit, if issued, would have consisted of shares of common stock and certain warrants to purchase common stock. On March 2, 2016, we announced the termination of the Exchange Offer. None of the Units were accepted for exchange in the Unit Exchange Offer.

Reasons for this Exchange Offer

We believe that the variable number of shares currently issuable upon a cashless exercise of Series A Warrants creates significant market uncertainty and downward pressure on the market value of our common stock. The purpose of the Exchange Offer is to replace as many Series A Warrants as possible with Series B Warrants, which feature a fixed number of shares issuable upon a cashless exercise. We believe this exchange will create more certainty and transparency in the market for our common stock and our capital structure, which we believe will benefit our stockholders. See “General Terms of the Exchange Offer.”

We are permitting all current holders of Series A Warrants, to tender their Series A Warrants and receive the Series B Warrants through this Exchange Offer. You should read the discussions under the headings “General Terms of the Exchange Offer,” and “Description of Series B Warrants Included in the Exchange Offer,” respectively, for more information about the Exchange Offer.

INTERESTS OF CERTAIN PERSONS IN THE EXCHANGE OFFER

Joshua Kornberg, our President, Chief Executive Officer and Interim Chairman of the Board, holds 11,112 Series A Warrants. Mr. Kornberg intends to tender all of his Series A Warrants for Series B Warrants in the Exchange Offer. Other than Mr. Kornberg, none of our officers or directors or their respective affiliates beneficially owns any of the Series A Warrants and, therefore, will not participate in the Exchange Offer.

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this prospectus, including our financial statements and related notes.

Risks Related to Our Business

We will require additional financing to finance operating expenses and fulfill our business plan. Such financing will be dilutive. Our independent public accounting firm has indicated in their audit opinion, contained in our financial statements, that they have serious doubts about our ability to remain a going concern.

We have not achieved profitability and anticipate that we will continue to incur net losses at least through the first two quarters of 2016. We had revenues of \$654,000 in 2015, but we had negative operating cash flows of \$7.5 million. In August 2015, we received proceeds of \$13.5 million (net of commissions but before payment of expenses) as a result of our public offering. During the remainder of 2015, we paid \$5.8 million in cash to cover accrued debts and obligations, most of which were required to be paid upon completion of the offering or were considered past due. Our cash balance was \$4.9 million as of December 31, 2015, and our accounts payable and accrued expenses were an aggregate \$1.5 million. We are currently incurring negative operating cash flows of approximately \$275,000 per month. Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories.

As of December 31, 2015, the Company had no debt. We will require additional funding to finance operating expenses and to invest in our sales organization and new product development and to enter the international marketplace. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means. If we are successful in securing adequate funding we plan to make significant capital or equipment investments, and we will also continue to make human resource additions over the next 12 months. Such additional financing will be dilutive to existing stockholders, and there is no assurance that such financing will be available upon acceptable terms. If such financing or adequate funds from operations are not available, we will be forced to limit our business activities, which will have a material adverse effect on our results of operations and financial condition.

As a result of the above factors, our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements included in this prospectus, that they have serious doubts about our ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources.”

Our limited operating history makes evaluation of our business difficult.

We were formed on April 23, 2002 and to date have generated only moderate revenue year by year. Our ability to implement a successful business plan remains unproven and no assurance can be given that we will ever generate sufficient revenues to sustain our business. We have a limited operating history which makes it difficult to evaluate our performance. You must consider our prospects in light of these risks and the expenses, technical obstacles, difficulties, market penetration rate and delays frequently encountered in connection with the development of new businesses. These factors include uncertainty as to whether we will be able to:

- Be successful in uncertain markets;
- Respond effectively to competitive pressures;
- Successfully address intellectual property issues of others;
- Protect and expand our intellectual property rights; and
- Continue to develop and upgrade our products.

Our business is dependent upon proprietary intellectual property rights, which if we were unable to protect, could have a material adverse effect on our business.

We rely on a combination of patent, trade secret and other intellectual property rights and measures to protect our intellectual property. We currently own and may in the future own or license additional patent rights or trade secrets in the U.S. with non-provisional patents elsewhere in the world that cover certain of our products. We rely on patent laws and other intellectual property laws, nondisclosure and other contractual provisions and technical measures to protect our products and intangible assets. These intellectual property rights are important to our ongoing operations and no assurance can be given that any measure we implement will be sufficient to protect our intellectual property rights. Also, with respect to our trade secrets and proprietary know-how, we cannot be certain that the confidentiality agreements we have entered into with employees will not be breached, or that we will have adequate remedies for any breach. We may lose the protection afforded by these rights through patent expirations, legal challenges or governmental action. If we cannot protect our rights, we may lose our competitive advantage if these patents were found to be invalid in the jurisdictions in which we sell or plan to sell our products. The loss of our intellectual property rights could have a material adverse effect on our business.

If we become subject to intellectual property actions, this could hinder our ability to deliver our products and services and our business could be negatively impacted.

We may be subject to legal or regulatory actions alleging intellectual property infringement or similar claims against us. Companies may apply for or be awarded patents or have other intellectual property rights covering aspects of our technologies or businesses. Moreover, if it is determined that our products infringe on the intellectual property rights of third parties, we may be prevented from marketing our products. While we are currently not subject to any material intellectual property litigation, any future litigation alleging intellectual property infringement could be costly, particularly in light of our limited resources. Similarly, if we determine that third parties are infringing on our patents or other intellectual property rights, our limited resources may prevent us from litigating or otherwise taking actions to enforce our rights. Any such litigation or inability to enforce our rights could require us to change our business practices, hinder or prevent our ability to deliver our products and services, and result in a negative impact to our business. Expansion of our business via product line enhancements or new product lines to drive increased growth in current or new markets may be inhibited by the intellectual property rights of our competitors and/or suppliers. Our inability to successfully mitigate those factors may significantly reduce our market opportunity and subsequent growth.

We face significant competition, including competition from companies with considerably greater resources than ours, and if we are unable to compete effectively with these companies, our market share may decline and our business could be harmed.

Our industry is highly competitive with numerous competitors ranging from well-established manufacturers to innovative start-ups. A number of our competitors have significantly greater financial, technological, engineering, manufacturing, marketing and distribution resources than we do. Their greater capabilities in these areas may enable them to compete more effectively on the basis of price and production and more quickly develop new products and technologies.

We estimate that the total market for surgical suction canisters is approximately \$94 million and we estimate the total cost of using surgical canisters is greater than \$94 million because this amount does not include the labor to handle the canisters, disposal costs and solidifying compounds commonly used to minimize exposure to health care workers. Our competitors include Cardinal Health, Inc., a medical manufacturer and distributor, and Stryker Instruments, a wholly owned subsidiary of Stryker Corporation, which has a leading position in our market. Both of these competitors are substantially larger than our company and are better capitalized than we are.

Companies with significantly greater resources than ours may be able to reverse engineer our products and/or circumvent our intellectual property position. Such action, if successful, would greatly reduce our competitive advantage in the marketplace.

We believe that our ability to compete successfully depends on a number of factors, including our technical innovations of unlimited suction and unlimited capacity capabilities, our innovative and advanced research and development capabilities, strength of our intellectual property rights, sales and distribution channels and advanced manufacturing capabilities. We plan to employ these and other elements as we develop our products and technologies, but there are many other factors beyond our control. We may not be able to compete successfully in the future, and increased competition may result in price reductions, reduced profit margins, loss of market share and an inability to generate cash flows that are sufficient to maintain or expand our development and marketing of new products, which could adversely impact the trading price of the shares of our common stock.

Our business is subject to intense governmental regulation and scrutiny, both in the U.S. and abroad.

The production, marketing, and research and development of our product is subject to extensive regulation and review by the FDA and other governmental authorities both in the United States and abroad. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record keeping. If we do not comply with applicable regulatory requirements, violations could result in warning letters, non-approvals, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Periodically, legislative or regulatory proposals are introduced that could alter the review and approval process relating to medical products. It is possible that the FDA will issue additional regulations further restricting the sale of our present or proposed products. Any change in legislation or regulations that govern the review and approval process relating to our current and future products could make it more difficult and costly to obtain approval for new products, or to produce, market, and distribute existing products.

If our product is not accepted by our potential customers, it is unlikely that we will ever become profitable.

The medical industry has historically used a variety of technologies for fluid waste management. Compared to these conventional technologies, our technology is relatively new, and the number of companies using our technology is limited. The commercial success of our product will depend upon the widespread adoption of our technology as a preferred method by hospitals and surgical centers. In order to be successful, our product must meet the technical and cost requirements for these facilities. Market acceptance will depend on many factors, including:

- the willingness and ability of customers to adopt new technologies;
- our ability to convince prospective strategic partners and customers that our technology is an attractive alternative to conventional methods used by the medical industry;
- our ability to select and execute agreements with effective distributors to market and sell our product; and
- our ability to assure customer use of the Skyline proprietary cleaning fluid and in-line filter.

Because of these and other factors, our product may not gain market acceptance or become the industry standard for the health care industry. The failure of such companies to purchase our products would have a material adverse effect on our business, results of operations and financial condition.

If demand for our product is unexpectedly high, there is no assurance that there will not be supply interruptions or delays.

We are currently manufacturing the STREAMWAY FMS, following GMP compliance regulations of the FDA, at our own facility and anticipate the capability of producing the STREAMWAY FMS in sufficient quantities for future near term sales. We have contracted with a manufacturing company that can manufacture products at higher volumes. However, if demand for our product is unexpectedly high, there is no assurance that we or our manufacturing partners will be able to produce the product in sufficiently high quantity to satisfy demands. Any supply interruptions or inadequate supply would have a material adverse effect on our results of operations.

We are dependent on a few key executive officers for our success. Our inability to retain those officers would impede our business plan and growth strategies, which would have a negative impact on our business and the value of an investment.

Our success depends on the skills, experience and performance of key members of our management team. We heavily depend on our management team: Joshua Komberg, our President, Chief Executive Officer and Interim Chairman of the Board, David O. Johnson, our Chief Operating Officer, and Bob Myers, our Chief Financial Officer. We have entered into employment agreements with all members of our senior management team and we may expand the relatively small number of executives in our company. Were we to lose one or more of these key individuals, we would be forced to expend significant time and money in the pursuit of a replacement, which could result in both a delay in the implementation of our business plan and the diversion of our limited working capital. We can give you no assurance that we can find satisfactory replacements for these key individuals at all, or on terms that are not unduly expensive or burdensome to our company.

Our success is dependent on our ability to attract and retain technical personnel, sales and marketing personnel, and other skilled management.

Our success depends to a significant degree on our ability to attract, retain and motivate highly skilled and qualified personnel. Failure to attract and retain necessary technical, sales and marketing personnel and skilled management could adversely affect our business. If we fail to attract, train and retain sufficient numbers of these highly qualified people, our prospects, business, financial condition and results of operations will be materially and adversely affected.

Costs incurred because we are a public company may affect our profitability.

As a public company, we incur significant legal, accounting, and other expenses, and we are subject to the SEC's rules and regulations relating to public disclosure that generally involve a substantial expenditure of financial resources. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC, requires changes in corporate governance practices of public companies. We expect that full compliance with such rules and regulations will significantly increase our legal and financial compliance costs and make some activities more time-consuming and costly, which may negatively impact our financial results. To the extent our earnings suffer as a result of the financial impact of our SEC reporting or compliance costs, our ability to develop an active trading market for our securities could be harmed.

Risks Related to Our Securities

There is currently a limited public trading market for our common stock and we cannot assure you that a more active public trading market for our common stock will develop or be sustained. Even if a market further develops, you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.

There is currently a limited public trading market for our common stock. The numbers of institutions or persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or nonexistent. This situation may be attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume. Even if we came to the attention of such persons, they tend to be risk averse and may be reluctant to follow a relatively unproven company such as ours or purchase or recommend the purchase of our shares until such time as we become more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot assure you that an active public trading market for our common stock will develop or be sustained.

Limitations on director and officer liability and indemnification of our officers and directors by us may discourage stockholders from bringing suit against a director.

Our certificate of incorporation and bylaws provide, with certain exceptions as permitted by governing state law, that a director or officer shall not be personally liable to us or our stockholders for breach of fiduciary duty as a director, except for acts or omissions which involve intentional misconduct, fraud or knowing violation of law, or unlawful payments of dividends. These provisions may discourage stockholders from bringing suit against a director for breach of fiduciary duty and may reduce the likelihood of derivative litigation brought by stockholders on our behalf against a director. In addition, our certificate of incorporation and bylaws may provide for mandatory indemnification of directors and officers to the fullest extent permitted by governing state law.

We do not expect to pay dividends for the foreseeable future, and we may never pay dividends.

We currently intend to retain any future earnings to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including but not limited to, our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. In addition, our ability to pay dividends on our common stock may be limited by state law. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize certain returns on their investment.

Our stock may be thinly traded.

Our common stock has been thinly traded, meaning there has been a low volume of buyers and sellers of the shares. Through this registration statement, we went public without the typical initial public offering procedures which usually include a large selling group of broker-dealers who may provide market support after going public. Thus, we will be required to undertake efforts to develop market recognition and support for our shares of common stock in the public market. The price and trading volume of our registered common stock cannot be assured. The numbers of institutions or persons interested in purchasing our registered common stock at or near ask prices at any given time may be relatively small or non-existent. This situation may be attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days, weeks or months when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price.

We cannot give you any assurance that a broader or more active public trading market for our common stock will develop or be sustained.

The application of the “penny stock” rules to our common stock could limit the trading and liquidity of the common stock and adversely affect the market price of our common stock.

As long as the trading price of our common stock is below \$5.00 per share, the open-market trading of our common stock will be subject to the “penny stock” rules, unless we otherwise qualify for an exemption from the “penny stock” definition. The “penny stock” rules impose additional sales practice requirements on certain broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with net assets in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 together with their spouse). These regulations, if they apply, require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. Under these regulations, certain brokers who recommend such securities to persons other than established customers or certain accredited investors must make a special written suitability determination regarding such a purchaser and receive such purchaser’s written agreement to a transaction prior to sale. These regulations may have the effect of limiting the trading activity of our common stock, reducing the liquidity of an investment in our common stock and increasing the transaction costs for sales and purchases of our common stock as compared to other securities.

Shares eligible for future sale may adversely affect the market.

From time to time, certain stockholders may be eligible to sell some or all of their shares of common stock pursuant to Rule 144, promulgated under the Securities Act subject to certain limitations. In general, pursuant to Rule 144 as in effect as of the date of this registration statement, a stockholder (or stockholders whose shares are aggregated) who has satisfied the applicable holding period and is not deemed to have been one of our affiliates at the time of sale, or at any time during the three months preceding a sale, may sell their shares of common stock. Any substantial sale, or cumulative sales, of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities.

We expect volatility in the price of our common stock, which may subject us to securities litigation.

If established, the market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the indefinite future. In addition, there is no assurance that the price of our common stock will not be volatile. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

Speculative nature of Series A Warrants.

The Series A Warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock for a limited period of time. Specifically, each Series A Warrant is exercisable for one share of common stock at an initial cash exercise price of \$4.95 per share or, in lieu of paying the exercise price in cash, holders may elect a cashless exercise whereby the holder would receive a number of shares equal to the Black Scholes Value (as defined herein). The Series A Warrants will expire on the fifth anniversary of the Issuance Date after which time they would have no further value. For additional information, see "Description of Securities – Description of Securities Sold in Public Offering of Units – Series A Warrants Included in the Units" on page 92 of this prospectus. Moreover, following this offering, the market value of the Series A Warrants is uncertain and there can be no assurance what the market value of the Series A Warrants will be. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the Series A Warrants, and consequently, whether it will ever be profitable for holders of the Series A Warrants to exercise the Series A Warrants.

Holders of our Series B Convertible Preferred Stock and Series A Warrants have no rights as a common stockholder until such holders convert their Series B Convertible Preferred Stock or exercise their Series A Warrants and acquire our common stock.

Until holders of our Series B Convertible Preferred Stock and Series A Warrants acquire shares of our common stock upon conversion or exercise, as the case may be, such holders will have no rights with respect to shares of our common stock underlying such Series B Convertible Preferred Stock and Series A Warrants. Upon conversion of the Series B Convertible Preferred Stock or exercise of the Series A Warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the conversion or exercise date.

Speculative nature of Series B Warrants

The Series B Warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock for a limited period of time. Specifically, each Series B Warrant entitles the registered holder to purchase one share of our common stock upon a cashless exercise. For additional information, see "Description of Series B Warrants Included in the Exchange Offer" on page 90 of this prospectus.

Holders of our Series B Warrants will have no rights as a common stockholder until such holders exercise their Series B Warrants and acquire our common stock.

Until holders of our Series B Warrants acquire shares of our common stock upon exercise, such holders will have no rights with respect to shares of our common stock underlying such Series B Warrants. Upon exercise of the Series B Warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Our Board of Directors' ability to issue undesignated preferred stock and the existence of anti-takeover provisions may depress the value of our common stock.

Our authorized capital includes 20 million shares of preferred stock. Of this amount, 18,950 shares have been designated as Series B Convertible Preferred Stock and the remaining authorized shares are undesignated preferred stock. Our Board of Directors has the power to issue any or all of the shares of undesignated preferred stock, including the authority to establish one or more series and to fix the powers, preferences, rights and limitations of such class or series, without seeking stockholder approval. Further, as a Delaware corporation, we are subject to provisions of the Delaware General Corporation Law regarding "business combinations." We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board of Directors to issue undesignated stock and the anti-takeover provisions of Delaware law, as well as any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of the company not approved by our Board of Directors. As a result, our stockholders may lose opportunities to dispose of their shares at favorable prices generally available in takeover attempts or that may be available under a merger proposal and the market price, voting and other rights of the holders of common stock may also be affected.

Future sales and issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We also expect that significant additional capital will be needed in the future to continue our planned operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. In addition, in the past, we have issued warrants to acquire shares of common stock. To the extent these warrants are ultimately exercised, you will sustain further dilution.

Certain features of the Series A Warrants may substantially accelerate the issuance of dilutive shares of our common stock.

Our Series A Warrants allow the cashless exercise of the Series A Warrants for a number of shares that increases as the trading market price of our common stock decreases, subject to a floor price of \$0.43. The potential for such dilutive exercise of the Series A Warrants may depress the price of common stock regardless of our business performance, and could encourage short selling by market participants, especially if the trading price of our common stock begins to decrease. If the Exchange Offer is not completed or a significant number of Series A Warrants remain outstanding following the Exchange Offer, the cashless exercise of a large number of the Series A Warrants, if the price of our common stock decreases significantly, would result in significant dilution.

If completed, the Exchange Offer will have a dilutive effect.

If the Exchange Offer is completed, the resulting issuance of common stock will have a dilutive effect. If all outstanding Series A Warrants are tendered in the Exchange Offer, then such holders of Series A Warrants will receive an aggregate of 32,203,297 Series B Warrants. If all of such Series B Warrants were fully exercised, such Warrant Shares would represent, in the aggregate, approximately 39% of our common stock, based on an aggregate of 82,241,077 shares outstanding.

Future sales of our common stock in the public market may cause our stock price to decline and impair our ability to raise future capital through the sale of our equity securities.

There are a substantial number of shares of our common stock held by stockholders who owned shares of our capital stock prior to this offering that may be able to sell in the public market upon expiration of the 90-day lock-up agreements they signed in connection with the Company's public offering which was consummated in August 2015. Sales by such stockholders of a substantial number of shares could significantly reduce the market price of our common stock.

The Series A Warrants contain a cashless exercise feature with the potential for a higher dilutive issuance of Common Stock, which could adversely affect the value of the Common Stock.

The Series A Warrants, described in Note 3 to the Financial Statements included in this report under “Stockholders’ Deficit, Stock Options and Warrants,” can be exercised starting February 2016. The Series A Warrants contain a cashless exercise feature that provides for the issuance of a number of shares of our common stock that increases as the trading market price of our common stock decreases, subject to a floor price of \$0.43. Approximately 3,390,935 Series A Warrants have been exercised in cashless exercises as of March 11, 2016, resulting in the issuance of 34,053,653 shares of common stock. If all of the remaining 4,189,105 Series A Warrants that were issued as part of the Units sold in the Offering and part of the Units issued on August 31, 2015 were exercised pursuant to a cashless exercise and the closing bid price of our common stock as of the two trading days prior to the time of such exercise was \$0.43 per share or less and the Black Scholes Value were \$4.3246 (the Black Scholes Value as of March 11, 2016), then a total of approximately 42,130,704 shares of our common stock would be issued to the holders of such Series A Warrants. The potential for such dilutive exercise of the Series A Warrants may depress the price of our common stock regardless of the Company’s business performance, and could encourage short selling by market participants, especially if the trading price of our common stock begins to decrease.

There is no assurance of a public trading market, and public offering prices were arbitrarily determined.

Prior to this Exchange Offer, there has been no public market for the Series B Warrants, and there can be no assurance that an active trading market for the Series B Warrants will develop or, if developed, be sustained after the Exchange Offer. The terms of the Series B Warrants have been arbitrarily determined by negotiations between the Company and the Dealer Manager, and do not necessarily bear any relationship to the Company’s assets, book value, results of operations or any other generally accepted criteria of value.

From our inception, through December 2013, our shares and other securities were issued in violation of the preemptive rights of existing stockholders, which could result in claims against us.

In 2013, it was brought to the attention of our management and Board of Directors that the Company was subject to preemptive rights under Minnesota corporate law, because the articles of incorporation did not “opt out” and deny them. Prior to our reincorporation in Delaware in December 2013 the Company issued shares of common stock and other equity securities on numerous occasions to raise capital and for other purposes and, to our knowledge; we never complied with the Minnesota preemptive rights statute in connection with such issuances. Starting in December 2013, stockholders no longer had preemptive rights. In connection with issuances of securities prior to that time, we may be still subject to the claims of previous and current stockholders based on violations of their preemptive rights; the risk and magnitude of these claims are uncertain. If there are any future claims, we intend to vigorously defend against such claims; however, there can be no assurance that the Company would not be liable for damages or other remedies that might have a material adverse effect on the Company’s financial condition or results of operations.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

All statements contained in this prospectus, other than statements of historical facts, that address future activities, events, or developments, are forward-looking statements, including, but not limited to, statements containing the words “believe,” “anticipate,” “expect,” and words of similar import. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. Whether actual results will conform to the expectations and predictions of management, however, is subject to a number of risks and uncertainties that may cause actual results to differ materially. Such risks are in the section herein entitled “Risk Factors,” and in our previous SEC filings.

Consequently, all of the forward-looking statements made in this prospectus are qualified by these cautionary statements, and there can be no assurance that the actual results anticipated by management will be realized or, even if substantially realized, that they will have the expected consequences to or effects on our business operations.

USE OF PROCEEDS

Because this transaction is an offer to holders to exchange their outstanding Series A Warrants for Series B Warrants, there is no source of funds or other cash consideration being paid to us to from those tendering Series A Warrants pursuant to the Exchange Offer. We will not receive any cash proceeds from the issuance of the Series B Warrants or from the exercise of the Series B Warrants. We estimate that the total amount of cash required to complete the transactions contemplated by the Exchange Offer, including the payment of any fees, expenses and other related amounts incurred in connection with the transactions will be approximately \$1,000,000. We expect to have sufficient funds to complete the transactions contemplated by the Exchange Offer and to pay fees, expenses and other related amounts from our cash on hand.

PRICE RANGE OF COMMON STOCK

The Series A Warrants are not listed for trading on any market.

Our common stock is listed on The NASDAQ Capital Market under the symbol "SKLN." Prior to August 31, 2015, our common stock was quoted by the OTCQB under the symbol "SKLN.QB." The following table sets forth the high and low bid information for our common stock for each quarter within our last two fiscal years as reported by The NASDAQ Capital Market or the OTCQB, as applicable. The bid prices reflect inter-dealer quotations, do not include retail markups, markdowns, or commissions, and do not necessarily reflect actual transactions. These prices reflect the 1:75 reverse stock split of our outstanding shares effected on October 24, 2014, as well as rounding.

Common Stock

| | <u>High</u> | <u>Low</u> |
|---|-------------|------------|
| 2016 | | |
| Quarter ending March 31, 2016 (through March 16, 2016) | \$ 3.80 | \$ 0.17 |
| 2015 | | |
| Quarter ended December 31, 2015 | 6.76 | 2.31 |
| Quarter ended September 30, 2015 | 5.78 | 2.75 |
| Quarter ended June 30, 2015 | 7.15 | 2.00 |
| Quarter ended March 31, 2015 | 7.00 | 2.00 |
| 2014 | | |
| Quarter ended December 31, 2014 | 10.88 | 3.25 |
| Quarter ended September 30, 2014 | 18.00 | 5.25 |
| Quarter ended June 30, 2014 | 14.25 | 7.95 |
| Quarter ended March 31, 2014 | 21.75 | 13.13 |

As of March 16, 2016, the closing price for shares of our common stock was \$0.21 per share on The NASDAQ Capital Market.

Holders

As of March 16, 2016, there were approximately 145 stockholders of record of our Common Stock and 2 holders of record of the Series B Preferred Stock and 2 holders of record of Series A Warrants.

DIVIDEND POLICY

We follow a policy of retaining earnings, if any, to finance the expansion of our business. We have not paid, and do not expect to declare or pay, cash dividends in the foreseeable future.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this prospectus. Our discussion includes forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations, and intentions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth under the "Special Note Regarding Forward-Looking Statements," "Business," and "Risk Factors" sections in this prospectus.

Overview

We were incorporated in Minnesota in April 2002 under the name BioDrain Medical, Inc. Effective August 6, 2013, the Company changed its name to Skyline Medical Inc. Pursuant to an Agreement and Plan of Merger dated effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly-owned subsidiary, with such Delaware corporation as the surviving corporation of the merger. We manufacture an environmentally conscientious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. Since our inception in 2002, we have invested significant resources into product development. We believe that our success depends upon converting the traditional process of collecting and disposing of infectious fluids from the operating rooms of medical facilities to our wall-mounted Fluid Management System ("FMS") and use of our proprietary cleaning fluid and filter kit.

We currently have one regional sales manager to sell the STREAMWAY FMS. In 2014 we signed a contract with an independent distributor covering New York and surrounding areas as well as, three other independent contracting groups handling parts of the Midwest, the Southeast and Oklahoma.

Since inception, we have been unprofitable. We incurred net losses of approximately \$4.8 million and \$6.8 million for the years ended December 31, 2015, and December 31, 2014, respectively. As of December 31, 2015 and December 31, 2014, we had an accumulated deficit of approximately \$40.5 million and \$35.6 million, respectively. We received approval from the FDA in April 2009 to commence sales and marketing activities of the STREAMWAY FMS system and shipped the first system in 2009. However, there was no significant revenue prior to 2011, primarily due to lack of funds to build and ship the product.

In the first quarter of 2014, the Company commenced sales of an updated version of the STREAMWAY FMS, which provides a number of enhancements to the existing product line including a more intuitive and easier to navigate control screen, data storage capabilities, and additional inlet ports on the filters, among other improvements. This updated version utilizes improved technology, including the capability for continuous flow and continuous suctioning, as covered by our provisional patent application filed in 2013 and our non-provisional patent application filed in January 2014. We have sold ninety-four STREAMWAY units to date.

We expect the revenue for STREAMWAY FMS units to increase significantly at such time as the hospitals approve the use of the units for their applications and place orders for billable units. We also expect an increase in trial based units. Trial basis units are either installed in or hung on the hospital room wall. The unit is connected to the hospital plumbing and sewer systems, as well as, the hospital vacuum system. The unit remains on the customer site for 2 – 4 weeks, as contracted, at no cost to the customer. However, the customer does purchase the disposable kits necessary to effectively operate the units. Once the trial period has expired the unit is either returned to the Company or purchased by the customer. If purchased, at that time, the Company invoices the customer based upon a contracted price negotiated prior to the trial.

We have never generated sufficient revenues to fund our capital requirements. We have funded our operations through a variety of debt and equity instruments. See "Liquidity and Capital Resources – Financing Transaction" below. In 2014, we completed private placements of Series A Preferred Stock and convertible notes raising aggregate gross proceeds of \$3,530,000. In September 2014 we commenced a public offering that was delayed, and we did not complete our public offering until August 2015. During that period of time, due to limited funding and continued operating losses, we curtailed our operations and delayed our expenditures to stay in operation. These factors negatively affected our sales in late 2014 and the full year 2015. Our future cash requirements and the adequacy of available funds depend on our ability to sell our products and the availability of future financing to fulfill our business plans. See "Plan of Financing; Going Concern Qualification" below.

As a company, our limited history of operations makes prediction of future operating results difficult. We believe that period to period comparisons of our operating results should not be relied on as predictive of our future results.

Results of Operations

Comparison of Year Ended December 31, 2015 with Year Ended December 31, 2014

Revenue. We recorded revenue of \$654,000 in 2015, compared to \$952,000 in 2014. Revenue in 2015 included the sale of twenty STREAMWAY systems and disposable supplies to operate the STREAMWAY. The revenue in 2014 included the sale of forty-four STREAMWAY systems and disposable supplies to operate the STREAMWAY. Our revenues and product sales declined in 2015 due to the delay in our public offering until August 2015, which caused us to curtail our operations and delay our expenditures. These factors negatively impacted sales throughout 2015.

Cost of sales. Cost of sales was \$304,000 in 2015 compared to \$385,000 in 2014. The gross profit margin was 54% in 2015 and 60% in 2014. As our revenue has increased and we honed in on parts for the STREAMWAY, we were better able to maximize our margins through advanced purchasing at larger volumes. The Company also developed ways to reduce costs through tooling parts and purchasing different components that improved the STREAMWAY Systems while costing less. However, in 2015, our sharp decline in sales negatively impacted our ability to leverage costs and negatively impacted our profit margin. Also, in 2015, margins were negatively affected as we absorbed the cost of replacing fifteen units of the original STREAMWAY generation model with its newer iteration initially rolled out in the second quarter of 2014.

General and Administrative expense. General and administrative (G&A) expense primarily consists of management salaries, professional fees, consulting fees, travel expense, administrative fees and general office expenses.

G&A expense decreased to \$3,399,000, for 2015 from \$4,883,000 in 2014. The \$1,484,000 decrease in G&A expenses for 2015, compared to 2014, is primarily due to higher expenses for financings and legal proceedings in 2014, as well as our efforts to curtail expenses in 2015. Our legal expenses decreased by \$1.1 million, because in 2015 the majority of our legal expenses were in association with our public offering and were therefore capitalized as appropriate. By comparison, in 2014 legal fees were higher due to our two private placements and certain legal disputes. Other decreases included \$204,000 in salaries and payroll taxes; \$329,000 in miscellaneous expenses in 2014 relating to a legal settlement; \$269,000 related to finders fees associated with fund raising in 2014; \$218,000 in payroll taxes, penalty and interest originally accrued in 2014 but not incurred; \$60,000 in investor relations costs and \$59,000 in recruiting fees. These decreases were partially offset by increases in 2015 that included increased expenses of \$475,000 due to an extension fee for the convertible notes issued in 2015 and 2014; \$216,000 in bonuses; \$79,000 in stock based and investor's stock compensation as a result of employee options issued; and \$52,000 in corporate insurance expenses.

Operations expense. Operations expense primarily consists of expenses related to product development and prototyping and testing in the Company's current stage.

Operations expense decreased to \$847,000 in 2015 compared to \$973,000 in 2014. The \$126,000 decrease in operations expense in 2015 was primarily due to decreases of \$52,000 in salaries and payroll taxes; \$133,000 in research and development expenses as a result of curtailed operations; \$59,000 in consulting; and \$30,000 in reduced shipping expenses. These decreases were partially offset by increases in 2015 that included \$82,000 in bonuses; \$45,000 in miscellaneous expenses for inventory adjustments and obsolescence; and \$28,000 for stock based compensation as a result of employee options issued.

Sales and marketing expense. Sales and marketing expense consists of expenses required to sell products through independent reps, attendance at trade shows, product literature and other sales and marketing activities.

Sales and marketing expenses decreased to \$504,000 in 2015 compared to \$1,178,000 in 2014. The \$674,000 decrease is a result of a \$335,000 decrease in salaries, payroll taxes and benefits due to a reduced sales staff; \$99,000 decreased commissions for less sales in 2015; \$158,000 for reduced bonuses; and \$71,000 in travel expenses.

Interest Expense. Interest expense increased to \$391,000 in 2015 compared to \$377,000 in 2014. The \$14,000 increase was a result of the convertible notes issued in 2014 and 2015.

Loss (gain) on valuation of equity-linked financial instruments. The Company realized a \$0 gain on valuation of equity-linked financial instruments in 2015 compared to a gain of \$12,000 in 2014 resulting in expiration of certain older warrants in 2014.

Liquidity and Capital Resources

Cash Flows for the Year Ended December 31, 2015

Net cash used in operating activities was \$7,487,000 for 2015, compared with net cash used of \$3,371,000 for 2014. In August 2015, we received proceeds of \$13.5 million (net of commissions but before payment of expenses) as a result of our public offering. During the remainder of 2015, we paid \$5.8 million in cash to cover accrued debts and obligations, most of which were required to be paid upon completion of the offering or were considered past due. These payments included: premium paid plus interest to redeem convertible notes as agreed with the holders to induce the redemption at a rate of 140% of principal: \$616,000; past due payrolls and taxes for employees: \$1,420,000; and past due amounts upon agreed upon legal settlements, including interest and penalties: \$916,000. In addition, the Company decreased payables by paying an aggregate \$3,900,000 in cost of goods to vendors for past due amounts for production of our product and in past due professional fees.

Cash flows used in investing activities was \$61,000 for 2015 and \$121,000 in 2014. Our investment expenses in 2015 were primarily for intangibles associated with our patents.

Net cash provided by financing activities was \$12,388,000 for 2015 compared to net cash provided of \$3,407,000 for 2014. In the second quarter of 2015 the Company received cash for two convertible notes totaling \$250,000. The Company completed a public offering on August 31, 2015 raising a net \$13,555,003. This was partially offset by redeeming the convertible notes issued in 2014 and 2015 with a remaining principal amount of \$933,074 not including accrued interest and redemption premiums.

Liquidity, Plan of Financing and Going Concern Qualification

Since our inception, we have incurred significant losses, and our accumulated deficit was approximately \$40.5 million as of December 31, 2015. Our operations from inception have been funded with private placements of convertible debt securities and equity securities, in addition to a past bank loan (not currently outstanding) and a qualified public offering raising a net \$13,555,003, after deducting underwriting discounts, commissions and expenses. We currently have no outstanding bank debt and no secured indebtedness.

We have not achieved profitability and anticipate that we will continue to incur net losses at least through the first two quarters of 2016.

We had revenues of \$654,000 in 2015, but we had negative operating cash flows of \$7.5 million. In August 2015, we received proceeds of \$13.5 million, after deducting underwriting discounts, commissions and expenses, as a result of our public offering. During the remainder of 2015, we paid \$5.8 million in cash to cover accrued debts and obligations, most of which were required to be paid upon completion of the offering or were considered past due. Our cash balance was \$4.9 million as of December 31, 2015, and our accounts payable and accrued expenses were an aggregate \$1.5 million. We are currently incurring negative operating cash flows of approximately \$275,000 per month. Although we are attempting to curtail our expenses, there is no guarantee that we will be able to reduce these expenses significantly, and expenses for some periods may be higher as we prepare our product for broader sales, increase our sales efforts and maintain adequate inventories.

As of December 31, 2015, the Company had no debt. We will require additional funding to finance operating expenses and to invest in our sales organization and new product development and to enter the international marketplace. We will attempt to raise these funds through equity or debt financing, alternative offerings or other means. If we are successful in securing adequate funding we plan to make significant capital or equipment investments, and we will also continue to make human resource additions over the next 12 months. Such additional financing will be dilutive to existing stockholders, and there is no assurance that such financing will be available upon acceptable terms. If such financing or adequate funds from operations are not available, we will be forced to limit our business activities, which will have a material adverse effect on our results of operations and financial condition.

As a result of the above factors, our independent registered public accounting firm has indicated in their audit opinion, contained in our financial statements included in this annual report on Form 10-K, that they have serious doubts about our ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern.

Financing Transactions

We have funded our operations through a combination of debt and equity instruments. We have funded our operations through an early bank loan (since repaid), and a variety of debt and equity offerings.

Series A Preferred Stock. On February 4, 2014, we raised \$2,055,000 in gross proceeds from a private placement of Series A Convertible Preferred Stock. The investors purchased 20,550 Preferred Shares, and warrants (the "Warrants") initially to acquire an aggregate of approximately 21,334 shares of Common Stock. The Warrants were initially exercisable at an exercise price of \$24.38 per share and expire after five years from the Closing Date. In August 2014, because the Common Stock was not listed on the Nasdaq Stock Market, the New York Stock Exchange, or the NYSE MKT within 180 days of the closing date, the Company was required to issue 61,542 additional Warrants. As a result of not reaching certain sales goals by January 2015, the number of shares of Common stock for which such Warrant may be exercised were increased 2.5 times under the terms of the Warrants; these additional Warrants were subsequently canceled in connection with the Unit Exchange described below. The Warrants are exercisable on any day or after the date of issuance, and have a term of five years. However, a holder is prohibited from exercising a Warrant if, as a result of such exercise, the holder, together with its affiliates, would exceed Certain limitations on conversion so that the holder will not own more than 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of the Warrants held by the applicable holder, with the percentage subject to increase in certain circumstances.

The Preferred Shares were initially convertible at the option of the holder into the number of shares of Common Stock determined by dividing the stated value of the Preferred Shares being converted by the conversion price of \$19.50, reduced in July 2015 to \$9.75 per share, subject to adjustment for stock splits, reverse stock splits and similar recapitalization events. The Preferred Shares were entitled to receive dividends on a pari passu basis with the Common Stock, when, and if declared. Upon any liquidation, dissolution or winding-up of the Company, after the satisfaction in full of the debts of the Company and the payment of any liquidation preference owed to the holders of senior preferred shares, the holders of the Series A Preferred Shares were entitled to receive, prior and in preference to the holders of any junior securities, an amount equal to \$2,055,000 times 1.2, plus all declared but unpaid dividends.

On August 31, 2015, the Company completed the Unit Exchange as described below under "Public Offering of Units – Unit Exchange." After the Unit Exchange, there were no shares of Series A Preferred Stock outstanding.

2014 and 2015 Sales of Convertible Notes and Warrants.

From July through September 2014, we issued approximately \$1.8 million original principal amount (subsequently reduced to approximately \$1.6 million aggregate principal amount in accordance with their terms) of convertible promissory notes (the “2014 Convertible Notes”) and warrants exercisable for shares of our common stock for an aggregate purchase price of \$1,475,000 in private placements. Of this amount, we issued to SOK Partners, LLC, an affiliate of the Company, \$122,196 original principal amount of the 2014 Convertible Notes and warrants exercisable for 5,431 shares of our common stock for an aggregate purchase price of \$100,000. In April and May 2015, we issued and sold to a private investor additional Convertible Notes in an aggregate original principal amount of \$275,000 for an aggregate purchase price of \$250,000, containing terms substantially similar to the 2014 Convertible Notes (the “2015 Convertible Notes” and, together with the 2014 Convertible Notes, the “Convertible Notes”). No warrants were issued with the 2015 Convertible Notes. The Warrants issued to the purchasers of the 2014 Convertible Notes are exercisable on any day on or after the date of issuance and have an exercise price of \$12.38 per share, subject to adjustment, and a term of five years from the date of issuance. The holders, will not be entitled, by virtue of being holders of the Warrants, to vote, to consent, to receive dividends, to receive notice as stockholders with respect to any meeting of stockholders for the election of the Company’s directors or any other matter, or to exercise any rights whatsoever as our stockholders. If, however, the Company decides to declare a dividend or make distributions of its assets, the holders will be entitled to such distribution to the same extent that the holder’s would have participated therein if the holder had held the number of shares of Common Stock acquirable upon complete exercise of the Warrants. At any time in connection with certain events relating to a change of control, the Company or the successor entity (as the case may be) may be required to purchase the Warrants from the holder in an amount equal to the Black Scholes Value (as defined in the Warrants).

In August of 2014, as a result of the Company filing a resale registration statement and the SEC declaring it effective within certain time periods, (1) the outstanding principal amount of the 2014 Convertible Notes was reduced from \$1,802,395 to \$1,603,270 (without any cash payment by the Company) and any accrued and unpaid interest with respect to such portion of the principal amount of the Notes that was extinguished was similarly extinguished, and (2) the number of shares of Common Stock issuable upon the exercise of the related Warrants was reduced from 80,106 shares of Common Stock to 71,257 shares of Common Stock (without any cash payment by the Company). In connection with this reduction, the principal amount of the Convertible Note issued to SOK Partners, LLC was reduced to \$108,695 and the number of related warrants was reduced to 4,831 shares.

On August 31, 2015, in connection with the Offering, as described below, pursuant to an agreement with the holders of the Convertible Notes, the Company redeemed the remaining \$933,074 aggregate principal amount of Convertible Notes plus interest and a 40% redeemable premium, for a total payment of \$1,548,792. Of this amount, approximately \$167,031 was paid to its affiliates in redemption of their Convertible Notes. Each holder of the Convertible Notes agreed to the foregoing terms and entered into an Amendment to Senior Convertible Notes and Agreement with the Company. As of September 30, 2015, none of the Convertible Notes were outstanding.

Public Offering of Units

On August 31, 2015 (the “Issuance Date”), the Company completed a public offering (the “Offering”) of 1,666,667 Units (the “Units”) as described below. The public offering price in the Offering was \$9.00 per Unit, and the purchase price for the underwriter of the Offering (the “Underwriter”) was \$8.28 per Unit, resulting in an underwriting discount and commission of \$0.72 (or 8.00%) per Unit and total net proceeds to the Company before expenses of \$13.8 million. The Company had granted the Underwriter an option for a period of 45 days to purchase up to an additional 250,000 Units solely to cover over-allotments. The Underwriter chose not to purchase any additional Units under the over-allotment option. The Company paid to the Underwriter a non-accountable expense allowance equal to 1% of the gross proceeds of the Offering and agreed to reimburse expenses incurred by the Underwriter up to \$70,000. On August 31, 2015, as a result of the consummation of the Offering and the issuance of the 228,343 Exchange Units in the Unit Exchange described below, the Company issued a total of 1,895,010 Units, comprised of a total of aggregate of 1,895,010 shares of Common Stock, 1,895,010 shares of Series B Preferred Stock and 7,580,040 Series A Warrants.

Each Unit consisted of one share of common stock, par value \$0.01 per share (the “Common Stock”), one share of Series B Convertible Preferred Stock (“Series B Preferred Stock”) and four Series A Warrants. The shares of Common Stock, the shares of Series B Preferred Stock and the Series A Warrants that comprise the Units automatically separated on February 29, 2016.

Series A Warrants. The Series A Warrants separated from the Series B Convertible Preferred Stock and the Common Stock included within the Units as described above and are currently exercisable. The Series A Warrants will terminate on August 31, 2020. Each Series A Warrant is exercisable into one share of Common Stock at an initial cash exercise price of \$4.95 per share. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Common Stock and the exercise price.

Holders may exercise Series A Warrants by paying the exercise price in cash or, in lieu of payment of the exercise price in cash, by electing to receive a number of shares of Common Stock equal to the Black Scholes Value (as defined below) based upon the number of shares the holder elects to exercise. The number of shares of Common Stock to be delivered will be determined according to the following formula, referred to as the “Cashless Exercise.”

$$\text{Total Shares} = (A \times B) / C$$

Where:

- Total Shares is the number of shares of Common Stock to be issued upon a Cashless Exercise.
- A is the total number of shares with respect to which the Series A Warrant is then being exercised.
- B is the Black Scholes Value (as defined below).
- C is the closing bid price of the Common Stock as of two trading days prior to the time of such exercise, provided that in no event may “C” be less than \$0.43 per share (subject to appropriate adjustment in the event of stock dividends, stock splits or similar events affecting the Common Stock).

As defined in the Series A Warrants, “Black Scholes Value” means the Black Scholes value of an option for one share of Common Stock at the date of the applicable Cashless Exercise, as such Black Scholes Value is determined, calculated using the Black Scholes Option Pricing Model obtained from the “OV” function on Bloomberg utilizing (i) an underlying price per share equal to 55% of the Unit price, or \$4.95 per share, (ii) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the remaining term of the Series A Warrant as of the applicable Cashless Exercise, (iii) a strike price equal to the exercise price in effect at the time of the applicable Cashless Exercise, (iv) an expected volatility equal to 135% and (v) a remaining term of such option equal to five years (regardless of the actual remaining term of the Series A Warrant). In the event that the Black Scholes Pricing Model from the “OV” function on Bloomberg is unavailable, the Company will calculate the Black Scholes Value in good faith, which calculation shall be definitive.

The Black Scholes Value (as defined above) as of March 11, 2016 was \$4.3246, and the closing bid price of Common Stock as of March 11, 2016, was \$0.18. Therefore, an exercise on that date would have resulted in the issuance of 10.06 shares of Common Stock for each Series A Warrant. Approximately 3,390,935 Series A Warrants have been exercised in cashless exercises as of March 11, 2016, resulting in the issuance of 34,053,653 shares of Common Stock. If all of the remaining 4,189,105 Series A Warrants that were issued as part of the Units sold in the Offering and part of the Units issued on August 31, 2015 were exercised pursuant to a cashless exercise and the closing bid price of our common stock as of the two trading days prior to the time of such exercise was \$0.43 per share or less and the Black Scholes Value were \$4.3246 (the Black Scholes Value as of March 11, 2016), then a total of approximately 42,130,704 shares of our common stock would be issued to the holders of such Series A Warrants. The potential for such dilutive exercise of the Series A Warrants may depress the price of our common stock regardless of the Company’s business performance, and could encourage short selling by market participants, especially if the trading price of our common stock begins to decrease.

The Series A Warrants will not be exercisable or exchangeable by the holder of such warrants to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company, determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the regulations promulgated thereunder.

In addition to (but not duplicative of) the adjustments to the exercise price and the number of shares of Common Stock issuable upon exercise of the Series A Warrants in the event of stock dividends, stock splits, reorganizations or similar events, the Series A Warrants provide for certain adjustments if the Company, at any time prior to the three year anniversary of the Issuance Date, (1) declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to all or substantially all of the holders of shares of Common Stock at any time after the Issuance Date, or (2) grants, issues or sells any options, convertible securities or rights to purchase stock, warrants, securities or other property pro rata to all or substantially all of the record holders of any class of shares of Common Stock. Further, if at any time a Series A Warrant is outstanding, the Company consummates any fundamental transaction, as described in the Series A Warrants and generally including any consolidation or merger into another corporation, or the sale of all or substantially all of our assets, or other transaction in which the Common Stock is converted into or exchanged for other securities or other consideration, the holder of any Series A Warrants will thereafter receive, the securities or other consideration to which a holder or the number of shares of Common Stock then deliverable upon the exercise or exchange of such Series A Warrants would have been entitled upon such consolidation or merger or other transaction.

Unit Purchase Option. The Company, in connection with the Offering, entered into a Unit Purchase Option Agreement, dated as of August 31, 2015 (the "Unit Purchase Option"), pursuant to which the Company granted the Underwriter the right to purchase from the Company up to a number of Units equal to 5% of the Units sold in the Offering (or up to 83,333 Units) at an exercise price equal to 125% of the public offering price of the Units in the Offering, or \$11.25 per Unit. The Unit Purchase Option expires on August 25, 2018.

Series B Preferred Stock. Each share of Series B Preferred Stock is convertible into one shares of Common Stock (subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events) on the six month anniversary of the Issuance Date or on the date of an Early Separation. In addition, the Series B Preferred Stock will automatically convert into shares of common stock upon the occurrence of a fundamental transaction, as described in the certificate of designations for the Series B Preferred Stock but including mergers, sales of the company's assets, changes in control and similar transactions. The Series B Preferred Stock is not convertible by the holder of such preferred stock to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company. The Series B Preferred Stock has no voting rights, except for the right to approve certain amendments to the certificate of designations or similar actions. With respect to payment of dividends and distribution of assets upon liquidation or dissolution or winding up of the Company, the Series B Preferred Stock shall rank equal to the common stock of the Company. No sinking fund has been established for the retirement or redemption of the Series B Preferred Stock.

Unit Exchange. On February 4, 2014, the Company raised \$2,055,000 in gross proceeds from a private placement of 20,550 shares of Series A Convertible Preferred Stock, par value \$0.01, with a stated value of \$100 per share (the "Series A Preferred Shares") and warrants to purchase shares of the Company's common stock. The Series A Preferred Shares and warrants were sold to investors pursuant to a Securities Purchase Agreement, dated as of February 4, 2014. On August 31, 2015, the Company issued a total of 228,343 Units (the "Exchange Units") in exchange for the outstanding Series A Preferred Stock which were then cancelled pursuant to an agreement with the holders of the Series A Preferred Shares. The warrants that were issued in connection with the issuance of the Series A Preferred Shares remained outstanding; however, the warrant amounts were reduced so that the warrants are exercisable into an aggregate of 84,770 shares of the Company's common stock. The Exchange Units were exempt from registration under Section 3(a)(9) of the Securities Act. On August 31, 2015, the Company filed a termination certificate with the Delaware Secretary of State. Following that date there were no shares of Series A Preferred Stock outstanding, and the previously authorized shares of Series A Preferred Stock resumed the status of authorized but unissued and undesignated shares of preferred stock of the Company.

Redemption of Convertible Notes. In connection with the closing of the Offering, \$933,074 aggregate principal amount of Convertible Notes plus interest and a 40% redeemable premium were redeemed for total payments of \$1,548,792. See Note 4. Of this amount, approximately \$167,031 was paid to its affiliates in redemption of their Convertible Notes.

Exchange Offer for Units

In January 2016 we commenced a registered offer (the “Exchange Offer”) to exchange, on a one-for-one basis, new units in exchange for the 1,895,010 outstanding units (the “Units”) that were issued in the Offering and the Unit Exchange. Each new unit, if issued, would have consisted of shares of common stock and certain warrants to purchase common stock. On March 2, 2016, we announced the termination of the Exchange Offer. None of the Units were accepted for exchange in the Exchange Offer.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our audited Financial Statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”). The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of our financial statements, the reported amounts of revenues and expenses during the reporting periods presented, as well as our disclosures of contingent assets and liabilities. On an on-going basis, we evaluate our estimates and assumptions, including, but not limited to, fair value of stock-based compensation, fair value of acquired intangible assets and goodwill, useful lives of intangible assets and property and equipment, income taxes, and contingencies and litigation.

We base our estimates and assumptions on our historical experience and on various other information available to us at the time that these estimates and assumptions are made. We believe that these estimates and assumptions are reasonable under the circumstances and form the basis for our making judgments about the carrying values of our assets and liabilities that are not readily apparent from other sources. Actual results and outcomes could differ from our estimates.

Our significant accounting policies are described in “Note 1 – Summary of Significant Accounting Policies,” in Notes to Financial Statements of this Annual Report on Form 10-K. We believe that the following discussion addresses our critical accounting policies and reflects those areas that require more significant judgments, and use of estimates and assumptions in the preparation of our Financial Statements.

Revenue Recognition. The Company recognizes revenue in accordance with the SEC’s Staff Account Bulletin Topic 13 Revenue Recognition and ASC 605 – Revenue Recognition.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectability is probable. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination based on the shipping terms of the transaction. Our standard terms specify that shipment is FOB Skyline and we will, therefore, recognize revenue upon shipment in most cases. This revenue recognition policy applies to shipments of our STREAMWAY FMS units as well as shipments of cleaning solution and filters. When these conditions are satisfied, we recognize gross product revenue, which is the price we charge generally to our customers for a particular product. Under our standard terms and conditions, there is no provision for installation or acceptance of the product to take place prior to the obligation of the customer. The customer’s right of return is limited only to our standard one-year warranty, whereby we replace or repair, at our option. We believe it would be rare that the STREAMWAY FMS unit or significant quantities of cleaning solution and/or filters may be returned. Currently we manufacture, test and ship the STREAMWAY FMS units from our own warehouse and can easily replace or repair units as needed. Additionally, since we buy the cleaning solution/filter kits from “turnkey” suppliers, we would have the right to replacements from the suppliers if this situation should occur.

Stock-Based Compensation. Effective January 1, 2006, we adopted ASC 718- *Compensation-Stock Compensation* (“ASC 718”). Under ASC 718 stock-based employee compensation cost is recognized using the fair value based method for all new awards granted after January 1, 2006 and unvested awards outstanding at January 1, 2006. Compensation costs for unvested stock options and non-vested awards that were outstanding at January 1, 2006, are being recognized over the requisite service period based on the grant-date fair value of those options and awards, using a straight-line method. We elected the modified-prospective method in adopting ASC 718 under which prior periods are not retroactively restated.

ASC 718 requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. We use the Black-Scholes option-pricing model which requires the input of significant assumptions including an estimate of the average period of time employees and directors will retain vested stock options before exercising them, the estimated volatility of our common stock price over the expected term, the number of options that will ultimately be forfeited before completing vesting requirements and the risk-free interest rate.

Because we do not have significant historical trading data on our common stock we relied upon trading data from a composite of 10 medical companies traded on major exchanges and 15 medical companies quoted by the OTC Bulletin Board to help us arrive at expectations as to volatility of our own stock when public trading commences. In 2013 the Company experienced significant exercises of options and warrants. The options raised \$6,500 in capital. Warrants exercised for cash produced \$1,330,000 of capital. In the case of options and warrants issued to consultants and investors we used the legal term of the option/warrant as the estimated term unless there was a compelling reason to use a shorter term. The measurement date for employee and non-employee options and warrants is the grant date of the option or warrant. The vesting period for options that contain service conditions is based upon management's best estimate as to when the applicable service condition will be achieved. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. The assumptions we use in calculating the fair value of stock-based payment awards represent our best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our equity-based compensation expense could be materially different in the future. See "Note 3 – Stockholders' Deficit, Stock Options and Warrants" in Notes to Financial Statements of this Annual Report on Form 10-K for additional information.

When an option or warrant is granted in place of cash compensation for services, we deem the value of the service rendered to be the value of the option or warrant. In most cases, however, an option or warrant is granted in addition to other forms of compensation and its separate value is difficult to determine without utilizing an option pricing model. For that reason we also use the Black-Scholes option-pricing model to value options and warrants granted to non-employees, which requires the input of significant assumptions including an estimate of the average period that investors or consultants will retain vested stock options and warrants before exercising them, the estimated volatility of our common stock price over the expected term, the number of options and warrants that will ultimately be forfeited before completing vesting requirements and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. Since we have no trading history in our common stock and no first-hand experience with how our investors and consultants have acted in similar circumstances, the assumptions we use in calculating the fair value of stock-based payment awards represent our best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our equity-based consulting and interest expense could be materially different in the future.

Since our common stock has no significant public trading history we were required to take an alternative approach to estimating future volatility and the future results could vary significantly from our estimates. We compiled historical volatilities over a period of 2 to 7 years of 10 small-cap medical companies traded on major exchanges and 15 medical companies in the middle of the market cap size range on the OTC Bulletin Board and combined the results using a weighted average approach. In the case of standard options to employees we determined the expected life to be the midpoint between the vesting term and the legal term. In the case of options or warrants granted to non-employees, we estimated the life to be the legal term unless there was a compelling reason to make it shorter.

Valuation of Intangible Assets. We review identifiable intangible assets for impairment in accordance with ASC 350- *Intangibles – Goodwill and Other*, whenever events or changes in circumstances indicate the carrying amount may not be recoverable. Our intangible assets are currently solely the costs of obtaining trademarks and patents. Events or changes in circumstances that indicate the carrying amount may not be recoverable include, but are not limited to, a significant change in the medical device marketplace and a significant adverse change in the business climate in which we operate. If such events or changes in circumstances are present, the undiscounted cash flows method is used to determine whether the intangible asset is impaired. Cash flows would include the estimated terminal value of the asset and exclude any interest charges. If the carrying value of the asset exceeds the undiscounted cash flows over the estimated remaining life of the asset, the asset is considered impaired, and the impairment is measured by reducing the carrying value of the asset to its fair value using the discounted cash flows method. The discount rate utilized is based on management's best estimate of the related risks and return at the time the impairment assessment is made. The Company wrote off the entire original STREAMWAY product patent of \$140,588 in June 2013. The balance represented intellectual property in the form of patents for our original STREAMWAY product. The Company's enhanced STREAMWAY product has a new patent pending, see "Patents and Intellectual Property."

Recent Accounting Developments

See Note 1—“Summary of Significant Accounting Policies—Recent Accounting Developments” included in this prospectus.

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented.

Off-Balance Sheet Transactions

We have not engaged in any off-balance sheet activities as defined in Item 303(a)(4) of Regulation S-K.

BUSINESS

Overview

We are a medical device company manufacturing an environmentally conscientious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. We own patent rights to our products, which consist of the STREAMWAY®FMS and distribute our products to medical facilities where bodily and irrigation fluids produced during surgical procedures must be contained, measured, documented, and disposed. Our products minimize the exposure potential to the healthcare workers who handle such fluids. Our goal is to create products that dramatically reduce staff exposure without significant changes to established operative procedures, historically a major stumbling block to innovation and product introduction. In addition to simplifying the handling of these fluids, we believe our technologies provide cost savings to facilities over the aggregate costs incurred today using the traditional canister method of collection, neutralization, and disposal. We sell our products through an experienced in-house sales force. The Company has one regional manager currently on staff. We also intend to utilize independent distributors in the United States and Europe, initially, and eventually to other areas of the world.

The STREAMWAY FMS is a wall mounted fully automated system that disposes of an unlimited amount of suctioned fluid providing uninterrupted performance for surgeons while virtually eliminating healthcare workers exposure to potentially infectious fluids found in the surgical environment. The system also provides an innovative way to dispose of aseptic fluid with no evac bottles, suction canisters, transport or risk of exposure. The Company also manufactures and sells two disposable products required for system operation: a bifurcated single procedure filter with tissue trap and a single use bottle of cleaning solution. Both items are used on a single procedure basis and must be discarded after use.

Skyline's virtually hands free direct-to-drain technology (a) significantly reduce the risk of healthcare worker exposure to these infectious fluids by replacing canisters, (b) further reduces the risk of worker exposure when compared to powered canister technology that requires transport to and from the operating room, (c) reduce the cost per procedure for handling these fluids, and (d) enhance the surgical team's ability to collect data to accurately assess the patient's status during and after procedures.

Skyline believes that the STREAMWAY FMS is unique to the industry in that it allows for continuous suction to the surgical field and provides unlimited capacity to the user so no surgical procedure will ever have to be interrupted to change canisters. It is wall mounted and takes up no valuable operating room space. The FMS can replace the manual process of collecting fluids in canisters and transporting and dumping in sinks outside of the operating room that is still being used by many hospitals and surgical centers.

Skyline believes its products provide substantial cost savings and improvements in safety in facilities that still use manual processes. In cases where healthcare organizations re-use canisters, the FMS cleaning process eliminates the need for cleaning of canisters for re-use. The FMS reduces the safety issues facing operating room nurses, the cost of the handling process, and the amount of infectious waste generated when the traditional method of disposing of canisters is used. The FMS is fully automated, does not require transport to and from the operating room and eliminates any canister that requires emptying. It is positioned to penetrate its market segment due to its virtually hands free operation, simple design, ease of use, continuous suction, continuous flow, unlimited capacity and efficiency in removal of infectious waste with minimal exposure of operating room personnel to potentially infectious material.

The Company was originally incorporated on April 23, 2002 in Minnesota as BioDrain Medical, Inc. Effective August 6, 2013, the Company changed its name to Skyline Medical Inc. Pursuant to an Agreement and Plan of Merger effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly-owned subsidiary, with such Delaware Corporation as the surviving corporation of the merger. On August 31, 2015, the Company completed a successful offering and concurrent uplisting to The NASDAQ Capital Market. Our address is 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. Our telephone number is 651-389-4800, and our website address is www.skylinemedical.com. Information on our website is not included or incorporated by reference in this prospectus.

Industry and Market Analysis

Infectious and Bio-hazardous Waste Management

There has long been recognition of the collective potential for ill effects to healthcare workers from exposure to infectious/bio-hazardous materials. Federal and state regulatory agencies have issued mandatory guidelines for the control of such materials, and in particular, bloodborne pathogens. The medical device industry has responded to this need by developing various products and technologies to limit exposure or to alert workers to potential exposure.

The presence of infectious materials is most prevalent in the surgical suite and post-operative care units where often, large amounts of bodily fluids, including blood, bodily and irrigation fluids are continuously removed from the patient during the surgical procedure. Surgical teams and post-operative care personnel may be exposed to these potentially serious hazards during the procedure via direct contact of blood materials or more indirectly via splash and spray.

According to the Occupational Safety and Health Administration (“OSHA”), workers in many different occupations are at risk of exposure to bloodborne pathogens, including Hepatitis B and C, and HIV/AIDS. First aid team members, housekeeping personnel, nurses and other healthcare providers are examples of workers who may be at risk of exposure.

In 1991, OSHA issued the Bloodborne Pathogens Standard to protect workers from this risk. In 2001, in response to the Needlestick Safety and Prevention Act, OSHA revised the Bloodborne Pathogens Standard. The revised standard clarifies (and emphasizes) the need for employers to select safer needle devices and to involve employees in identifying and choosing these devices. The revised standard also calls for the use of “automated controls” as it pertains to the minimization of healthcare exposure to bloodborne pathogens. Additionally, employers are required to have an exposure control plan that includes universal precautions to be observed to prevent contact with blood or other potentially infectious materials, such as implementing work practice controls, requiring personal protective equipment and regulating waste and waste containment. The exposure control plan is required to be reviewed and updated annually to reflect new or modified tasks and procedures, which affect occupational exposure and to reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens.

According to the American Hospital Association’s (AHA) Hospital Statistics, 2013 edition, America’s hospitals performed approximately 86 million surgeries. This number does not include the many procedures performed at surgery centers across the country.

The majority of these procedures produce potentially infectious materials that must be disposed with the lowest possible risk of cross-contamination to healthcare workers. Current standards of care allow for these fluids to be retained in canisters, located in the operating room where they can be monitored throughout the surgical procedure. Once the procedure is complete these canisters and their contents are disposed using a variety of methods all of which include manual handling and result in a heightened risk to healthcare workers for exposure to their contents. A Frost & Sullivan research report from April 24, 2006 estimates that 60 million suction canisters are sold each year and the estimated market value of canisters is upwards of \$120 million.

A study by the Lewin Group, prepared for the Health Industry Group Purchasing Association in April 2007, reports that infectious fluid waste accounts for more than 75% of U.S. hospitals biohazard disposal costs. The study also includes findings from a bulletin published by the University of Minnesota’s Technical Assistance Program. “A vacuum system that uses reusable canisters or empties directly into the sanitary sewer can help a facility cut its infectious waste volume, and save money on labor, disposal and canister purchase costs.” The Minnesota’s Technical Assistance Program bulletin also estimated that, in a typical hospital, “. . . \$75,000 would be saved annually in suction canister purchase, management and disposal cost if a canister-free vacuum system was installed.”

We expect the hospital surgery market to continue to increase due to population growth, the aging of the population, expansion of surgical procedures to new areas, for example, use of the endoscope, which requires more fluid management, and new medical technology.

There are currently approximately 40,000 operating rooms and surgical centers in the U.S. (AHA, Hospital Statistics, 2008). The hospital market has typically been somewhat independent of the U.S. economy; therefore we believe that our targeted market is not cyclical, and the demand for our products will not be heavily dependent on the state of the economy. We benefit by having our products address both the procedure market of nearly 51.6 million inpatient procedures (CDC, National Hospital Discharge Survey: 2010 table) as well as the hospital operating room market (approximately 40,000 operating rooms).

Current Techniques of Collecting Infectious Fluids

Typically, during the course of the procedure, fluids are continuously removed from the surgical site via wall suction and tubing and collected in large canisters (1,500 - 3,000 milliliters (ml) capacity or 1.5 – 3.0 liters) adjacent to the surgical table.

These canisters, made of glass or high impact plastic, have graduated markers on them allowing the surgical team to make estimates of fluid loss in the patient both intra-operatively as well as for post-operative documentation. Fluid contents are retained in the canisters until the procedure is completed or until the canister is full and needs to be removed. During the procedure the surgical team routinely monitors fluid loss using the measurement calibrations on the canister and by comparing these fluid volumes to quantities of saline fluid introduced to provide irrigation of tissue for enhanced visualization and to prevent drying of exposed tissues. After the procedure is completed the fluids contained in the canisters are measured and a calculation of total blood loss is determined. This is done to ensure no excess fluids of any type remain within the body cavity or that no excessive blood loss has occurred, both circumstances that may place the patient at an increased risk post-operatively.

Once total blood loss has been calculated, the healthcare personnel must dispose of the fluids. This is typically done by manually transporting the fluids from the operating room to a waste station and directly pouring the material into a sink that drains to the sanitary sewer where it is subsequently treated by the local waste management facility, a process that exposes the healthcare worker to the most risk for direct contact or splash exposure. Once emptied these canisters are placed in large, red pigmented, trash bags and disposed of as infectious waste – a process commonly referred to as “red-bagging.”

Alternatively, the canisters may be opened in the operating room and a gel-forming powder is poured into the canister, rendering the material gelatinous. These gelled canisters are then red-bagged in their entirety and removed to a bio-hazardous/infectious holding area for disposal. In larger facilities the canisters, whether pre-treated with gel or not, are often removed to large carts and transported to a separate special handling area where they are processed and prepared for disposal. Material that has been red-bagged is disposed of separately, and more expensively, from other medical and non-medical waste by companies specializing in that method of disposal.

Although all of these protection and disposal techniques are helpful, they represent a piecemeal approach to the problem of safely disposing of infectious fluids and fall short of providing adequate protection for the surgical team and other workers exposed to infectious waste. A major spill of fluid from a canister, whether by direct contact as a result of leakage or breakage, splash associated with the opening of the canister lid to add gel, while pouring liquid contents into a hopper, or during the disposal process, is cause for concern of acute exposure to human blood components—one of the most serious risks any healthcare worker faces in the performance of his or her job. Once a spill occurs, the entire area must be cleaned and disinfected and the exposed worker faces a potential of infection from bloodborne pathogens. These pathogens include, but are not limited to, Hepatitis B and C, HIV/AIDS, HPV, and other infectious agents. Given the current legal liability environment the hospital, unable to identify at-risk patients due to concerns over patient rights and confidentiality, must treat every exposure incident as a potentially infectious incident and treat the exposed employee according to a specific protocol that is both costly to the facility and stressful to the affected employee and his or her co-workers. In cases of possible exposure to communicable disease, the employee could be placed on paid administrative leave, frequently involving worker's compensation, and additional workers must be assigned to cover the affected employee's responsibilities. The facility bears the cost of both the loss of the affected worker and the replacement healthcare worker in addition to any ongoing health screening and testing of the affected worker to confirm if any disease has been contracted from the exposure incident. Canisters are the most prevalent means of collecting and disposing of infectious fluids in hospitals today. Traditional, non-powered canisters and related suction and fluid disposable products are exempt and do not require FDA clearance.

We believe that our virtually hands free direct-to-drain technology will (a) significantly reduce the risk of healthcare worker exposure to these infectious fluids by replacing canisters, (b) further reduce the risk of worker exposure when compared to powered canister technology that requires transport to and from the operating room, (c) reduce the cost per procedure for handling these fluids, and (d) enhance the surgical team's ability to collect data to accurately assess the patient's status during and after procedures.

In addition to the traditional canister method of waste fluid disposal, several new powered medical devices have been developed which address some of the deficiencies described above. MD Technologies, Inc., Domoch Medical Systems, Inc. (Zimmer), and Stryker Instruments have all developed systems that provide for disposal into the sanitary sewer without pouring the infectious fluids directly through a hopper disposal or using expensive gel powders and most are sold with 510(k) concurrence from the FDA. Most of these competing products continue to utilize some variant on the existing canister technology, and while not directly addressing the canister, most have been successful in eliminating the need for expensive gel and its associated handling and disposal costs. Our existing competitors that already have products on the market have a clear competitive advantage over us in terms of brand recognition and market exposure. In addition, the aforementioned companies have extensive marketing and development budgets that could overpower an early stage company like ours. We believe that Stryker Instruments has the dominant market share position.

Products

The STREAMWAY Fluid Management System ("FMS")

The STREAMWAY FMS suctions surgical waste fluid from the patient using standard surgical tubing. The surgical waste fluid passes through our proprietary disposable filters and into the STREAMWAY FMS. The STREAMWAY FMS maintains continuous suction to the surgical field at all times. A simple, easy to use Human Interface Display screen guides the user through the set up process, ensuring that a safe vacuum level is identified and set by the user for each procedure and additionally guides them through the cleaning process.

The STREAMWAY FMS is unique to our industry in that it allows for continuous suction to the surgical field and provides unlimited capacity to the user so no surgical procedure will ever have to be interrupted to change canisters. It is wall mounted and takes up no valuable operating room space.

The FMS will replace the manual process of collecting fluids in canisters and transporting and dumping in sinks outside of the operating room that is still being used by many hospitals and surgical centers. The manual process, involving canisters, requires that the operating room personnel open the canisters that contain waste fluid, often several liters, at the end of the surgical procedure and either add a solidifying agent or empty the canisters in the hospital drain system. Some facilities require that used canisters be cleaned by staff and reused. It is during these procedures that there is increased potential for contact with the waste fluid through splashing or spills. The FMS eliminates the use of canisters and these cleaning and disposal steps by collecting the waste fluid in the internal collection chamber and automatically disposing of the fluid with no handling by personnel. Each procedure requires the use of a disposable filter. At the end of each procedure, a proprietary cleaning fluid is attached to the FMS and an automatic cleaning cycle ensues, making the FMS ready for the next procedure. The cleaning fluid bottle is attached to the port on the FMS device. The cleaning fluid bottle and its contents are not contaminated and are used to clean the internal fluid pathway in the FMS device to which personnel have no exposure. During the cleaning cycle, the cleaning fluid is pulled from the bottle into the FMS, and then disposed in the same manner as the waste fluid from the surgical case. At the end of the cleaning cycle, the bottle is discarded. The filter and any suction tubing used during the procedure must be disposed of in the same manner as suction tubing used with the canister system. Handling of this tubing does present the potential for personnel exposure but that potential is minimal.

We believe our product provides substantial cost savings and improvements in safety in facilities that still use manual processes. In cases where healthcare organizations re-use canisters, the FMS cleaning process eliminates the need for cleaning of canisters for re-use. The FMS reduces the safety issues facing operating room nurses, the cost of the handling process, and the amount of infectious waste generated when the traditional method of disposing of canisters is used. The FMS is fully automated, does not require transport to and from the operating room and eliminates any canister that requires emptying. We believe it is positioned to penetrate its market segment due to its virtually hands free operation, simple design, ease of use, continuous suction, continuous flow, unlimited capacity and efficiency in removal of infectious waste with minimal exposure of operating room personnel to potentially infectious material.

In contrast to competitive products, the wall-mounted FMS does not take up any operating room floor space and it does not require the use of any external canisters or handling by operating room personnel. It does require a dedicated system in each operating room where it is to be used. The FMS is the only known direct-to-drain system that is wall-mounted and designed to collect, measure and dispose of, surgical waste. Other systems on the market are portable, meaning that they are rolled to the bedside for the surgical case and then rolled to a cleaning area, after the surgery is complete, and use canisters, which still require processing or require a secondary device (such as a docking station) to dispose of the fluid in the sanitary sewer after it has been collected. They are essentially powered canisters. A comparison of the key features of the devices currently marketed and the FMS is presented in the table below.

Key Feature Comparison

| Feature | Skyline Medical Inc. | Stryker Instruments | DeRoyal | Dornoch Medical Systems, Inc. (Zimmer) | MD Technologies, Inc. |
|--|-------------------------------------|--------------------------------|----------------|---|--------------------------------------|
| Portable to Bedside vs. Fixed Installation | Fixed | Portable | Fixed | Portable | Fixed |
| Uses Canisters | No | Yes | Yes | Yes | No |
| Secondary Installed Device Required for Fluid Disposal | No | Yes | Yes | Yes | No |
| Numeric Fluid Volume Measurement | Yes | Yes | No | Yes | Optional |
| Unlimited Fluid Capacity | Yes | No | No | No | Yes |
| Continuous, Uninterrupted Vacuum | Yes | No | No | No | No |
| Installation Requirements : | | | | | |
| Water | No | Yes | Yes | Yes | No |
| Sewer | Yes | Yes | Yes | Yes | Yes |
| Vacuum | Yes | No | No | No | Yes |

The FMS system may be installed on or in the wall during new construction or renovation or installed in a current operating room by connecting the device to the hospital’s existing sanitary sewer drain and wall suction systems. With new construction or renovation, the system will be placed in the wall and the incremental costs are minimal, limited to connectors to the hospital drain and suction systems (which systems are already required in an operating room), the construction of a frame to hold the FMS in position, and minimal labor. The fluid collection chamber is internal to the FMS unit and requires no separate installation. Based upon our consultations with several architects, we believe that there is no appreciable incremental expense in planning for the FMS system during construction.

For on-the-wall installation in a current operating room, the location of the FMS may be chosen based on proximity to the existing hospital drain and suction systems. Installation will require access to those systems through the wall and connection to the systems in a manner similar to that for within-the-wall installation. The FMS system is mounted on the wall using a mounting bracket supplied with the system and standard stud or drywall attachments.

Once installed, the FMS has inflow ports positioned on the front of the device that effectively replace the current wall suction ports most commonly used to remove fluids during surgery. Additionally, a disposable external filter, which is provided as part of our disposable cleaning kit, allows for expansion to additional inflow suction ports by utilizing one or two dual port filters.

Although the FMS is directly connected to the sanitary sewer, helping to reduce potential exposure to infectious fluids, it is possible that installation of the system will temporarily cause inconvenience and lost productivity as the operating rooms will need to be taken off-line temporarily.

One of the current techniques utilized by Stryker, Cardinal Health, and other smaller companies typically utilizes two to eight canisters positioned on the floor or on elaborate rolling containers with tubing connected to the hospital suction system and to the operative field. Once the waste fluids are collected, they must be transported out of the operating room and disposed of using various methods. These systems take up floor space in and around the operating room and require additional handling by hospital personnel, thereby increasing the risk of exposure to infectious waste fluids generated by the operating room procedure. Handling infectious waste in this manner is also more costly.

A summary of the features of the wall unit include:

- Minimal Human Interaction. The wall-mounted FMS provides a small internal reservoir that keeps surgical waste isolated from medical personnel and disposes the medical waste directly into the hospital sanitary sewer with minimal medical personnel interaction. This minimal interaction is facilitated by the automated electronic controls and computerized LCD touch-screen allowing for simple and safe single touch operation of the FMS.
- Fluid Measurement. The STREAMWAY System volume measurement allows for in-process, accurate measurement of blood/saline suctioned during the operative procedure, and eliminates much of the estimation of fluid loss currently practiced in the operating room. This is particularly important in minimally invasive surgical procedures, where accounting for all fluids, including saline added for the procedure, is vital to the operation. The surgical team can also view in real time the color of the extracted or evacuated fluid through the viewing window on the system.
- Cleaning Solution. A bottle of cleaning solution, proprietary to and sold by us, is used for the automated cleaning cycle at the conclusion of each procedure and prepares the STREAMWAY FMS for the next use, reducing operating room turnover time. The cleaning solution is intended to clean the internal tubing, pathways, and chamber within the system. The cleaning solution bottle is easily attached to the STREAMWAY FMS by inserting the bottle into the mount located on the front of the unit and inverting the bottle. The automated cleaning process takes less than five minutes and requires minimal staff intervention. The disposable cleaning fluid bottle collapses at the end of the cleaning cycle rendering it unusable; therefore it cannot be refilled with any other solution. The instructions for use clearly state that our cleaning fluid, and only our cleaning fluid, must be used with the STREAMWAY FMS following each surgical case. The warranty is voided if any other solution is used.
- Procedure Filters. One or two filters, depending on the type of procedure, will be used for every surgical procedure. The filter has been developed by us, is proprietary to the STREAMWAY FMS and is only sold by us. The filter is a two port, bifurcated, disposable filter that contains a tissue trap that allows staff to capture a tissue sample and send to pathology if needed. The filters are disposed of after each procedure. The cleaning fluid and filter are expected to be a substantial revenue generator for the life of the STREAMWAY FMS.
- Ease of Use. The FMS simply connects to the existing suction tubing from the operative field (causing no change to the current operative methods). Pressing the START button on the FMS touch screen enacts a step by step instruction with safety questions ensuring that the correct amount of suction is generated minimizing the learning curve for operation at the surgical site.
- Installation. We will arrange installation of the FMS products through a partnership or group of partnerships. Such partnerships will include, but not be limited to, local plumbers, distribution partners, manufacturer's representatives, hospital supply companies and the like. We will train our partners and standardize the procedure to ensure the seamless installation of our products. The FMS is designed for minimal interruption of operating room and surgical room utilization. Plug-and-play features of the design allow for almost immediate connection and hook up to hospital utilities for wall-mounted units allowing for quick start-up post-installation.

- **Sales Channel Partners.** The FMS is sold to end-users through a combination of independent stocking distributors, manufacturer's representatives, and direct sales personnel. We intend for all personnel involved in direct contact with the end-user will have extensive training and will be approved by Skyline. We plan to maintain exclusive agreements between Skyline and the sales channel partners outlining stocking expectations, sales objectives, target accounts and the like. Contractual agreements with the sales channel partners will be reviewed on an annual basis and expect that such agreements will contain provisions allowing them to be terminated at any time by Skyline based on certain specified conditions.
- **Competitive Pricing.** The list sales price to a hospital or surgery center is \$21,900 per system (one per operating room - installation extra) and \$24 per unit retail for the proprietary consumable kit to the U.S. hospital market.

Intellectual Property

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain protection of the proprietary aspects of our technology. We rely on a combination of patent, trade secret and other intellectual property rights and measures to protect our intellectual property.

We spent approximately \$261,000 in 2015 and \$394,000 in 2014 on research and development. On January 25, 2014 the Company filed a non-provisional PCT Application No. PCT/US2014/013081 claiming priority from the U.S. Provisional Patent Application, number 61756763 which was filed one year earlier on January 25, 2013. The Patent Cooperation Treaty ("PCT") allows an applicant to file a single patent application to seek patent protection for an invention simultaneously in each of the 148 member countries of the PCT, including the United States. By filing this single "international" patent application through the PCT system, it is easier and more cost effective than filing separate applications directly with each national or regional patent office in the various countries in which patent protection is desired.

Our PCT patent application is for an enhanced model of the surgical fluid waste management system. We utilize this enhanced technology in the updated version of the STREAMWAY FMS unit we began selling in the first quarter of 2014. We obtained a favorable International Search Report from the PCT searching authority indicating that the claims in our PCT application are patentable (i.e., novel and non-obvious) over the cited prior art. A feature claimed in the PCT application is the ability to maintain continuous suction to the surgical field while simultaneously measuring, recording and evacuating fluid to the facilities sewer drainage system. This provides for continuous operation of the STREAMWAY FMS unit in suctioning waste fluids, which means that suction is not interrupted during a surgical operation, for example, to empty a fluid collection container or otherwise dispose of the collected fluid. We believe that this continuous operation and unlimited capacity feature provides us with a significant competitive advantage, particularly on large fluid generating procedures. All competing products, except certain models of MD Technologies, have a finite fluid collection capacity necessitating that the device be emptied when capacity is reached during the surgical procedure. In the case of MD Technologies while some of their models may have an unlimited capacity their process is not truly continuous like the Company's system because it requires switching the vacuum containers when one becomes full. For example, when the first container becomes full, the vacuum is switched over to a second container in order to collect the fluid in the second container while the fluid in the first container is drained. When the second container becomes full, the vacuum is again switched back to the first container to collect fluid while the second container is drained, and so on. Even though the switching of the vacuum between containers is automated in certain MD Technology models, the automated switching is still believed to result in brief interruptions or reductions in suction during the surgical procedure.

The Company holds the following granted patents in the United States, and a pending application in the United States on its earlier models: US7469727, US8123731 and US Publication No. US20090216205 (collectively, the "Patents"). These Patents will begin to expire on August 8, 2023.

In general, the Patents are directed to a system and method for collecting waste fluid from a surgical procedure while ensuring there is no interruption of suction during the surgical procedure and no limit on the volume of waste fluid which can be collected. More particularly, the Patents claim a system and method in which waste fluid is suctioned or drawn into holding tanks connected to a vacuum source which maintains a constant negative pressure in the holding tanks. When the waste fluid collected in the holding tanks reaches a predetermined level, the waste fluid is measured and pumped from the holding tanks while maintaining the negative pressure. Therefore, because the negative pressure is maintained in the holding tanks, waste fluid will continue to be drawn into the holding tanks while the waste fluid is being pumped from the holding tanks. Thus, there is no limit to the volume of waste fluid which can be collected, and the suction at the surgical site is never interrupted during the surgical procedure.

We also rely upon trade secrets, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We seek to protect our trade secrets and proprietary know-how, in part, with confidentiality agreements with employees, although we cannot be certain that the agreements will not be breached, or that we will have adequate remedies for any breach.

The Disposable Kit

The disposable kit is an integral, critical component of the FMS and our total value proposition to the customer. It consists of a proprietary, pre-measured amount of cleaning solution in a plastic bottle that attaches to the FMS. The disposal cleaning kit also includes an in-line filter with single or multiple suction ports. The proprietary cleaning solution placed in the specially designed holder is attached and recommended to be used following each surgical procedure. Due to the nature of the fluids and particles removed during surgical procedures, the FMS is recommended to be cleaned following each use. Utilizing the available vacuum of the wall system, the proprietary cleaning fluid is drawn into the FMS to provide a highly effective cleaning process that breaks up bio-film at the cellular level. Proper cleaning is required for steady, dependable and repeated FMS performance and for maintenance of the warranty of the FMS.

Our disposables are a critical component of our business model. The disposables have the “razor blade business model” characteristic with an ongoing stream of revenue for every FMS unit installed, and revenues from the sale of the kits are expected to be significantly higher over time than the revenues from the sales of the unit. Our disposable, dual use filter is designed specifically for use only on our FMS. The filter is used only once per procedure followed by immediate disposal. Our operation instructions and warranty require that our filter is used for every procedure. There are no known off the shelf filters that will fit our FMS. We have developed a more effective and cost efficient filter, with intent to patent. We have exclusive distribution rights to the disposable fluid and facilitate the use of only our fluid for cleaning following procedures by incorporating a special adapter to connect the fluid to the connector on the FMS system. We will also tie the fluid usage, which we will keep track of with the FMS software, to the product warranty. While it could be possible for other manufacturers to provide fluids for utilization in this process, it would require that they manufacture an adapter compatible with our connector on the FMS, obtain a container that fits in the specially designed container holder on the FMS and perform testing to demonstrate that any other fluid would not damage the FMS. We believe that these barriers and the warranty control will allow us to achieve substantial revenue from our cleaning fluid, if we are able to sell a substantial number of FMS units. The instructions for use that accompanies the product will clearly state how the fluid is to be hooked up to the FMS machine. Further, a diagram on the FMS will also assist the user in attaching the fluid bottle to the machine. This will be a very simple task, and we do not anticipate that any training of operating room staff will be necessary.

All installations of our FMS product have been completed by either a hospital appointed service technician or a service and maintenance organization that is familiar with completing such installations in health care settings. We are exploring entering into an arrangement with one or more providers to provide installation services.

Corporate Strategy

Our strategy is focused on expansion within our core product and market segments, while utilizing a progressive approach to manufacturing and marketing to ensure maximum flexibility and profitability.

Our strategy is to:

- *Develop a complete line of wall-mounted fluid evacuation systems for use in hospital operating rooms, radiological rooms and free standing surgery centers as well as clinics and physicians' offices.* Initially, we have developed the FMS to work in hospital operating rooms and surgical centers. This device was developed for use with the wall vacuum suction currently installed in hospitals. Opportunities for future products include an FMS developed for post-operation and recovery rooms with multiple inlet ports and multiple volume measurements that may incorporate an on-board vacuum supply.

- *Provide products that greatly reduce healthcare worker and patient exposure to harmful materials present in infectious fluids and that contribute to an adverse working environment.* As one of the only stand-alone surgical fluid disposal systems directly connected to the sanitary sewer, the FMS could advance the manner in which such material is collected, measured and disposed of in operating rooms, post-operating recovery, emergency rooms and intensive care settings by eliminating the need to transport a device to the patient bedside and remove it for emptying and cleaning at the end of the procedure. We believe the cost of such exposures, measured in terms of human suffering, disease management costs, lost productivity, liability or litigation, will be, when properly leveraged, the strongest motivating factor for facilities looking at investing in the FMS line of products.
- *Utilize existing medical products independent distributors and manufacturer's representatives to achieve the desired market penetration.* Contacts have been established with several existing medical products distributors and manufacturer's representatives and interest has been generated regarding the sales of the FMS and cleaning kits.
- *Continue to utilize operating room consultants, builders and architects as referrals to hospitals and day surgery centers.* To date, the STREAMWAY System has achieved market acceptance through the installation of more than seventy-nine (79) FMS systems. The product has received numerous references from users and was also recognized by LifeScience Alley as a top ten finalist in their new technology showcase. Additionally, Skyline has become a member of Practice Greenhealth; highlighting the positive environmental impact of the STREAMWAY System.

Other strategies may also include:

- *Employing a lean operating structure, while utilizing the latest trends and technologies in manufacturing and marketing, to achieve both market share growth and projected profitability.*
- *Providing a leasing program and/or "pay per use" program as alternatives to purchasing.*
- *Providing service contracts to establish an additional revenue stream.*
- *Utilizing the manufacturing experience of our management team to develop sources of supply and manufacturing to reduce costs while still obtaining excellent quality. While cost is not a major consideration in the roll-out of leading edge products, we believe that being a low-cost provider will be important long term.*
- *Offering an innovative warranty program that is contingent on the exclusive use of our disposable kit to enhance the success of our after-market disposable products.*

Technology and Competition

Fluid Management for Surgical Procedures

The management of surgical waste fluids produced during and after surgery is a complex mix of materials and labor that consists of primary collection of fluid from the patient, transportation of the waste fluid within the hospital to a disposal or processing site and disposal of that waste either via incineration or in segregated landfills.

Once the procedure has ended, the canisters currently being used in many cases, and their contents must be removed from the operating room and disposed. There are several methods used for such disposal, all of which present certain risks to the operating room team, the crews who clean the rooms following the procedure and the other personnel involved in their final disposal. These methods include:

- *Direct Disposal Through the Sanitary Sewer.* In virtually all municipalities, the disposal of liquid blood may be done directly to the sanitary sewer where it is treated by the local waste management facility. This practice is approved and recommended by the EPA. In most cases these municipalities specifically request that disposed bio-materials not be treated with any known anti-bacterial agents such as glutaldehyde, as these agents not only neutralize potentially infectious agents but also work to defeat the bacterial agents employed by the waste treatment facilities themselves. Disposal through this method is fraught with potential exposure to the service workers, putting them at risk for direct contact with these potentially infectious agents through spillage of the contents or via splash when the liquid is poured into a hopper – a specially designated sink for the disposal of infectious fluids. Once the infectious fluids are disposed of into the hopper, the empty canister is sent to central processing for re-sterilization (glass and certain plastics) or for disposal with the bio-hazardous/infectious waste generated by the hospital (red-bagged).
- *Conversion to Gel for Red-Bag Disposal.* In many hospital systems the handling of this liquid waste has become a liability issue due to worker exposure incidents and in some cases has even been a point of contention during nurse contract negotiations. Industry has responded to concerns of nurses over splash and spillage contamination by developing a powder that, when added to the fluid in the canisters, produces a viscous, gel-like substance that can be handled more safely. After the case is completed and final blood loss is calculated, a port on the top of each canister is opened and the powder is poured into it. It takes several minutes for the gel to form, after which the canisters are placed on a service cart and removed to the red-bag disposal area for disposal with the other infectious waste. There are four major drawbacks to this system:
 - It does not ensure protection for healthcare workers, as there remains the potential for splash when the top of the canister is opened.
 - Based on industry pricing data, the total cost per canister increases by approximately \$2.00.
 - Disposal costs to the hospital increase dramatically as shipping, handling and landfill costs are based upon weight rather than volume in most municipalities. The weight of an empty 2,500 ml canister is about 1 pound. A canister and its gelled contents weigh about 7.5 pounds, and the typical cost to dispose of medical waste is approximately \$.30 - \$.50 per pound.
 - The canister filled with gelled fluid must be disposed; it cannot be cleaned and re-sterilized for future use.

Despite the increased cost of using gel and the marginal improvement in healthcare worker protection it provides, several hospitals have adopted gel as their standard procedure.

Drainage Systems

Several new medical devices have been developed which address some of the deficiencies described above. MD Technologies, Inc., Cardinal Health, Inc., Domo Medical Systems, Inc. (now Zimmer) and Stryker Instruments have all developed systems that provide disposal into the sanitary sewer without pouring the infectious fluids directly through a hopper disposal or using expensive gel powders. All of these newer products are currently sold with 510(k) exempt concurrence from the FDA. Most of these competing products incorporate an internal collection canister with finite capacity, and while not directly eliminating the need to transport a device to and from the surgical room, we believe most have been successful in eliminating the need for expensive gel and its associated handling and disposal costs.

Existing competitors, that already have products on the market, have a competitive advantage in terms of brand recognition and market exposure. In addition, the aforementioned companies have extensive marketing and development budgets that could overpower an early stage company like ours.

We believe that Stryker Instruments has the dominant market share position. We also believe competing products are used in select procedures and often in some, but not all, surgical procedures.

Current Competition, Technology, and Costs

Single Use Canisters

In the U.S., glass reusable containers are infrequently used as their high initial cost, frequent breakage and costs of reprocessing are typically more costly than single use high impact plastic canisters, even when disposal is factored in. Each single use glass canister costs roughly \$8.00 each while the high impact plastic canisters cost \$2.00 - \$3.00 each and it is estimated that a range of two to eight canisters are used in each procedure, depending on the operation.

Our FMS would replace the use of canisters and render them unnecessary, as storage and disposal would be performed automatically by the FMS. It should be noted that these canisters are manufactured by companies with substantially more resources than our Company. Cardinal Health, a very significant competitor, manufactures both single use canisters as well as a more automated fluid handling system that compete with us. Accordingly, faced with this significant competition, we may have difficulty penetrating this market. Our true competitive advantage, however, is our unlimited capacity, eliminating the need for any high volume cases to be interrupted for canister changeover.

Solidifying Gel Powder

The market potential for solidifying gel was estimated by industry publications at over \$100 million in 2002. This market is not yet fully realized, but many hospitals, responding to increased concerns over inadvertent worker exposure to liquid waste, are converting to this technology. It is clear that solidifying gels, while not providing complete freedom from exposure to healthcare workers do present a level of safety and peace of mind to the healthcare workers who handle gel-treated canisters. While several gel manufacturers proclaim that sterility of the contents is achieved with the use of their product, protocols continue to recommend that the red-bag procedure is followed when using these products. One significant drawback of the solidifying gels is that they increase the weight of the materials being sent to the landfill by a factor of five to seven times, resulting in a significant cost increase to the hospitals that elect to use the solidifying gels.

The FMS eliminates the need for solidifying gel, providing savings in both gel powder usage and associated landfill costs.

Sterilization and Landfill Disposal

Current disposal methods include the removal of the contaminated canisters (with or without the solidifying gel) to designated biohazardous/infectious waste sites. Previously many hospitals used incineration as the primary means of disposal, but environmental concerns at the international, domestic and local level have resulted in a systematic decrease in incineration worldwide as a viable method for disposing of blood, organs or materials saturated with bodily fluids. When landfill disposal is used, canisters are included in the general red-bag disposal and, when gel is used, comprise a significant weight factor. Where hopper disposal is still in use, most of the contents of the red-bag consist only of outer packaging of supplies used in surgery and small amounts of absorbent materials impregnated with blood and other waste fluid. These, incidentally, are retained and measured at the end of the procedure to provide a more accurate assessment of fluid loss or retention. Once at the landfill site, the red-bagged material is often steam-sterilized with the remaining waste being ground up and interred into a specially segregated waste dumpsite.

Handling Costs

Once the surgical team has finished the procedure, and a blood loss estimate is calculated, the liquid waste (with or without solidifying gels) is removed from the operating room and either disposed of down the sanitary sewer or transported to an infectious waste area of the hospital for later removal.

The FMS would significantly reduce the labor costs associated with the disposal of fluid or handling of contaminated canisters, as the liquid waste is automatically emptied into the sanitary sewer after measurements are obtained. We utilize the same suction tubing currently being used in the operating room, so no additional cost is incurred with our process. While each hospital handles fluid disposal differently, we believe that the cost of our cleaning fluid after each procedure will be less than the current procedural cost that could include the cost of canisters, labor to transport the canisters, solidifying powder, gloves, gowns, mops, goggles, shipping, and transportation, as well as any costs associated with spills that may occur due to manual handling.

A hidden but very real and considerable handling cost is the cost of infectious fluid exposure. A July 2007 research article published in *Infection Control Hospital Epidemiology* concluded that "Management of occupational exposures to blood and bodily fluids is costly; the best way to avoid these costs is by prevention of exposures." According to the article, hospital management cost associated with occupational blood exposure can, conservatively, be more than \$4,500 per exposure. Because of privacy laws, it is difficult to obtain estimates of exposure events at individual facilities; however, in each exposure the healthcare worker must be treated as a worse case event. This puts the healthcare worker through a tremendous amount of personal trauma, and the health care facility through considerable expense and exposure to liability and litigation.

Nursing Labor

Nursing personnel spend significant time in the operating room readying canisters for use, calculating blood loss and removing or supervising the removal of the contaminated canisters after each procedure. Various estimates have been made, and our management team estimates that the average nursing team spends twenty minutes pre-operatively and intra-operatively setting up, monitoring fluid levels and changing canisters as needed and twenty minutes post-operatively readying blood loss estimates or disposing of canisters. Estimates for the other new technologies reviewed have noted few cost savings to nursing labor.

The FMS would save nursing time as compared to the manual process of collecting and disposing of surgical waste. Set-up is as easy as attaching the suction tube to the inflow port of the FMS. Post-operative clean-up requires approximately five minutes, the time required to dispose of the suction tubing and disposable filter to the red-bag, calculate the patient's blood loss, attach the bottle of cleaning solution to the inlet port of the unit, initiate the cleaning cycle, and dispose of the emptied cleaning solution. The steps that our product avoids, which are typically involved with the manual disposal process include, canister setup, interpretation of an analog read out for calculating fluid, canister management during the case (i.e. swapping out full canisters), and then temporarily storing, transferring, dumping, and properly disposing of the canisters.

Competitive Products

Disposable canister system technology for fluid management within the operating room has gone virtually unchanged for decades. As concern for the risk of exposure of healthcare workers to bloodborne pathogens, and the costs associated with canister systems has increased, market attention has increasingly turned toward fluid management. The first quarter of 2001 saw the introduction of four new product entries within the infectious material control field. Stryker Instruments introduced the "Neptune™" system, offering a combination of bio-aerosol and fluid management in a portable two-piece system; Waterstone Medical (now DeRoyal) introduced the "Aqua Box™" stationary system for fluid disposal; Cardinal Health introduced the Orwell Fluid Collection and Disposal System; and Dornoch Medical Systems, Inc. (Zimmer) introduced the "Red Away™" stationary system for fluid collection and disposal. All companies, regardless of size, have their own accessory kits.

We differentiate from these competitors since we are completely direct-to-drain and have the most automatic, hands-free process of any of the systems currently on the market. Each of our competitors, with the exception of MD Technologies, Inc., has some significant manual handling involved in the process. For instance, some competing products require transport of the mobile unit to a docking port and then emptying of the fluid, while others require that the canister be manually transported to a more efficient dumping station. Regardless, most of our competitors require more human interaction with the fluid than our products do. Please refer to the chart included in the section headed as Products for a comparison of the key features of the devices currently marketed and the FMS.

Although the mobility associated with most of the competing products adds time and labor to the process and increases the chance of worker exposure to waste fluids, it also allows the hospital to purchase only as many mobile units needed for simultaneous procedures in multiple operating rooms. With the FMS, a unit must be purchased and installed in each room where it is intended to be used.

Marketing and Sales

Distribution

We sell the FMS and procedure disposables through various methods that include a direct sales force and independent distributors covering the vast majority of major U.S. markets. Currently we have one regional manager selling, and demoing the FMS for prospective customers and distributors, as well as, supporting our current customer base for disposable resupply. We are close to signing contracts with various hospital purchasing groups and have signed on independent distributors. Our targeted customer base includes nursing administration, operating room managers, CFOs, CEOs, risk management, and infection control. Other professionals with an interest in the product include physicians, nurses, biomedical engineering, anesthesiologists, imaging, anesthesiologists, human resources, legal, administration and housekeeping.

The major focus of our marketing efforts will be to introduce the FMS as a standalone device capable of effectively removing infectious waste and disposing of it automatically while providing accurate measurement of fluids removed, and also limiting exposure of the surgical team and healthcare support staff.

Governmental and professional organizations have become increasingly aggressive in attempting to minimize the risk of exposure by medical personnel to bloodborne pathogens. We believe that the FMS provides a convenient and cost effective way to collect and dispose of this highly contaminated material.

Our distributors may have installation and service capability, or we will contract those functions with an independent service/maintenance company. We have hired both distributors and service companies regarding these installation requirements. We have established extensive training and standards for the service and installation of the FMS to ensure consistency and dependability in the field. Users of the system require a minimal amount of training to operate the FMS. The instructions for use and the installation guide are included with every system along with a quick start guide, a troubleshooting manual and an on-board PLC controlling an intuitive touch screen with step by step instruction and safety features.

We have structured our pricing and relationships with distributors and/or service companies to ensure that these entities receive at least a typical industry level compensation for their activities.

Promotion

The dangers of exposure to infectious fluid waste are well recognized in the medical community. It is our promotional strategy to effectively educate medical staff regarding the risks of contamination using current waste collection procedures and the advantages of the FMS in protecting medical personnel from inadvertent exposure. We intend to leverage this medical awareness and concern with education of regulatory agencies at the local, state and federal levels about the advantages of the FMS.

We supplement our sales efforts with a promotional mix that include a number of printed materials, video support and a website. We believe our greatest challenge lies in reaching and educating the 1.6 million medical personnel who are exposed daily to fluid waste in the operating room or in other healthcare settings (OSHA, CPL 2-2.44C). These efforts require utilizing single page selling pieces, video educational pieces for technical education, use of scientific journal articles and a webpage featuring product information, educational materials, and training sites.

We support our sales organization by attending major scientific meetings where large numbers of potential users are in attendance. The theme of our trade show booths focus on education, the awareness of the hazards of infectious waste fluids and the Company's innovative solution to the problem. We have focused our efforts initially on the Association of Operating Room Nurses ("AORN") meetings, where the largest concentration of potential buyers and influencers are in attendance and the Radiological Society of North America Scientific Assembly and Annual Meeting. We have partnered with the Association for Radiologic & Imaging Nursing ("ARIN") and will be presenting in their April 2016 annual educational conference in Vancouver, British Columbia. We feature information on protection of the healthcare worker on our website as well as links to other relevant sites. We have invested in limited journal advertising for targeted audiences that have been fully identified. The initial thrust focuses on features of the product and ways of contacting the Company via the webpage or directly through postage paid cards or direct contact. Additionally, we will create a press release distribution to clinician-oriented periodicals for inclusion in their new product development columns. These periodicals will provide the reader with an overview of the FMS and will direct readers to pursue more information by direct contact with us by accessing our webpage.

Pricing

We believe prices for the FMS and its disposable procedure kit reflect a substantial cost savings to hospitals compared to their long-term procedure costs. Our pricing strategy ensures that the customer realizes actual cost savings when using the FMS versus replacing traditional canisters, considering the actual costs of the canisters and associated costs such as biohazard processing labor and added costs of biohazard waste disposal. Suction tubing that is currently used in the operating room will continue to be used with our system and should not be considered in the return on investment equation. Our cleaning solution's bottle is completely recyclable, and the selling price of the fluid is built into our cost analysis. In contrast, an operation using traditional disposal methods will often produce multiple canisters destined for biohazard processing. Once the canister has touched blood, it is considered "red bag" biohazard waste, whereas the cleaning fluid bottle used in the FMS can be recycled or disposed with the rest of the facility's plastics.

The FMS lists for \$21,900 per system (one per operating room – installation extra) and \$24 per unit retail for the proprietary disposable kit to the U.S. hospital market. By comparison, the disposal system of Stryker Instruments, one of our competitors, retails for approximately \$25,000 plus an \$8,000 docking station and requires a disposable component with an approximate cost of \$25 per procedure and a proprietary cleaning fluid (cost unknown per procedure). Per procedure cost of the traditional disposal process includes approximate costs of \$2 - \$3.00 per liter canister, plus solidifier at \$2 per liter canister, plus the biohazard premium disposal cost approximated at \$1.80 per liter canister. In addition, the labor, gloves, gowns, goggles, and other related material handling costs are also disposal expenses.

Installation is done by distributors, independent contractors, or in-house engineering at an estimated price of \$300 - \$1,000, depending on the operating room. Installation of the FMS requires access only to the hospital's sanitary sewer, vacuum suction, and electricity. To help facilities maintain their utilization rates, we recommend installation during off peak hours. In smaller facilities, an outside contractor may be called in, while larger institutions have their own installation and maintenance workforce. Installation time should not seriously impact the use of the operating room. Each FMS has an industry standard warranty period that can be extended through documented use of our disposables: one filter and one bottle of cleaning solution per procedure.

Engineering and Manufacturing

We are currently manufacturing the FMS in a leased facility. We have the capability to manufacture, test, house, ship and receive from our warehouse. We contracted a manufacturing company, Wair Products in Bloomington, Minnesota that meets our standards and requirements that can produce six times the amount of FMS systems produced in-house at our facility on a monthly basis as sales increase.

The disposables, including a bottle of proprietary cleaning solution and an in-line filter, is sourced through Diversified Manufacturing Corporation (cleaning solution) situated in Newport, Minnesota and MPP Corporation (filters), located in Osceola, Wisconsin that has tooled to manufacture our own newly designed disposable filter. We are pursuing intellectual property protection for these disposable products as well.

Government Regulation

To date, no regulatory agency has established exclusive jurisdiction over the area of biohazardous and infectious waste in healthcare facilities. Several organizations maintain oversight function concerning various aspects of pertinent technologies and methods of protection.

These agencies include:

- OSHA (Occupational Safety and Health Administration)
- EPA (Environmental Protection Agency)
- DOT (Department of Transportation)
- JCAHO (Joint Commission of Accreditation of Hospitals)
- NFPA (National Fire Protection Association)
- AIA (American Institute of Architects)
- AORN (Association of Operating Room Nurses)

Application for Electrical Safety Testing and Certification

We sought and achieved testing and certification to the IEC 60606-1 and IEC 60606-1-2, two internationally recognized standards.

The 6060101 & 60601-2 2nd edition certification for our STREAMWAY FMS is valid and enables us to continue to market and sell our product domestically.

A new standard; IEC 60601-1 3rd Edition Medical Device Safety Testing was adopted by the International Organization of Standards in 2005 and had a compliance date of June 2012 for OUS and December 31, 2013 for the U.S. This standard, which is now recognized by the U.S. FDA, includes a provision of risk management which the 2nd edition did not require. The purpose of these rules is to ensure that equipment manufacturers have safety, performance, and risk management control measures in place.

The EU & Canada required 60601-1 3rd Edition compliance for all product sold or currently on the market after June 2013. Any product that had previously been certified to the 60601-1 2nd generation standard was no longer allowed for use as the old standard was no longer recognized. This did not affect us as we did not sell internationally.

The U.S. FDA compliance date to meet the new standard was December 31, 2013. The major difference between the U.S. and the EU & Canadian market transition to the new standard is that the U.S. allows the 60601-1 2nd edition testing to be grandfathered in, allowing previously certified product to remain on the market. Any new product that will be tested after December 31, 2013 should be certified to the new 60601-1 3rd generation standard.

FDA Clearance under Section 510(k)

The FDA Center for Devices and Radiological Health requires 510(k) submitters to provide information that compares its new device to a marketed device of a similar type, in order to determine whether the device is substantially equivalent (“SE”).

This means that a manufacturer can submit a 510(k) comparing a new device to a device that has been found to be SE and the FDA can use this as evidence to determine whether the new device is SE to an already legally marketed device (or a “predicate device”). The ultimate burden of demonstrating the substantial equivalence of a new device to a predicate device remains with the 510(k) submitter, and in those occasions when the Center for Devices and Radiological Health is unfamiliar with certain aspects of the predicate device, the submitter will be required to provide information that substantiates a claim of substantial equivalence.

As a matter of practice, the Center for Devices and Radiological Health generally considers a device to be SE to a predicate device if, in comparison to the predicate device, (i) the new device has the same intended use, (ii) the new device has the same technological characteristics (i.e., same materials design, energy source), (iii) the new device has new technological characteristics that could not affect safety or effectiveness, or (iv) the new device has new technological characteristics that could affect safety or effectiveness, but there are accepted scientific methods for evaluating whether safety or effectiveness has been adversely affected and there is data to demonstrate that the new technological features have not diminished safety or effectiveness. Pre-market notification submissions are designed to facilitate these determinations.

The FDA requires, pursuant to a final regulation for Establishment Registration and Device Listing for Manufacturers of Devices, that a 510(k) premarket notification be submitted at least ninety days before marketing a device that: (1) is being introduced into distribution for the first time by that person or entity, or (2) is in distribution but is being significantly modified in design or use. A 510(k) submission must contain, among other things: (i) proposed labeling sufficient to describe the device's intended use; (ii) a description of how the device is similar to or different from other devices of comparable type, or information about what consequences a proposed device modification may have on the device's safety and effectiveness; and (iii) any other information necessary to determine whether the device is substantially equivalent. The FMS is a Class II device, which is less stringently reviewed as that of a Class III device. Our COO has numerous years' significant experience in the FDA clearance process and has a team of regulatory consultants with significant experience in the FDA clearance process.

We filed the 510(k) submission for clearance of the FMS device on March 14, 2009 and received written confirmation on April 1, 2009 that our 510(k) has been cleared by the FDA.

Following this 510(k) clearance by the FDA, we continue to be subject to the normal ongoing audits and reviews by the FDA and other governing agencies. These audits and reviews are standard and typical in the medical device industry, and we do not anticipate being affected by any extraordinary guidelines or regulations.

Employees

We have 12 employees, ten of whom are full-time, and two who are part-time.

Property

Our corporate offices are located at 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121. On January 28, 2013, the Company signed an amendment to the month to month lease originally signed on April 30, 2012. The lease as amended has a five-year term effective February 1, 2013 ending January 31, 2018. We lease 5,773 square feet at this location, of which 2,945 square feet is used for office space and 2,828 is used for manufacturing. Our lease is effective through January 31, 2018. We expect that this space will be adequate for our current office and manufacturing needs.

MANAGEMENT

Our directors and executive officers, their ages, their respective offices and positions, and their respective dates of election or appointment are as follows:

| Name | Age | Position | Date of Election or Appointment |
|----------------------|-----|--|---------------------------------|
| Joshua Kornberg | 42 | President, Chief Executive Officer and Interim Chairman of the Board | July 1, 2012 |
| Thomas J. McGoldrick | 74 | Director | 2005 |
| Andrew P. Reding | 45 | Director | 2006 |
| Carl Schwartz | 75 | Director | March 23, 2016 |
| David O. Johnson | 63 | Chief Operating Officer | July 1, 2012 |
| Bob Myers | 61 | Chief Financial Officer | July 1, 2012 |

Business Experience Descriptions

Set forth below is a summary of our executive officers' and directors' business experience for the past five years. Other than as described below, the experience and background of each of the directors, as summarized below, were significant factors in their previously being nominated as directors of the Company.

Josh Kornberg, President, Chief Executive Officer and Interim Chairman of the Board. Effective July 22, 2012, Mr. Kornberg was appointed as the Chief Executive Officer and President of the Company. Mr. Kornberg was appointed Interim Chairman of the Board on August 21, 2013. Mr. Kornberg was elected Interim President and Chief Executive Officer by the Board on April 23, 2012. Mr. Kornberg was elected to the Board on March 9, 2012. Mr. Kornberg is President and founding partner of Atlantic Partners Alliance (APA), a private equity fund based in New York. APA and its affiliates are significant stockholders of the Company. Prior to founding APA, Mr. Kornberg served as Chief Investment Officer of The Lightstone Group, a national private equity firm and Director of the Lightstone Value Plus REIT, a public company focused on commercial real estate. Mr. Kornberg worked in the capital markets group at Morgan Stanley, and also served as Vice President at The RREEF Funds, one of the leading global pension fund advisors. In December 2013, Mr. Kornberg was appointed to the Board of Directors of Prospect Park Capital Corporation a business development company currently trading on the Canadian TSX exchange. We believe Mr. Kornberg's experience as CEO of our Company, familiarity with our business, and extensive experience in the financial industry provide valuable insight on our Board.

Thomas J. McGoldrick, Director. Mr. McGoldrick has served as a Director of the Company since 2005. Prior to that, he served as Chief Executive Officer of Monteris Medical Inc. from November 2002 to November 2005. He has been in the medical device industry for over 30 years and was co-founder and Chief Executive Officer of Fastitch Surgical in 2000. Fastitch is a start-up medical device company with unique technology in surgical wound closure. Prior to Fastitch, Mr. McGoldrick was President and Chief Executive Officer of Minntech from 1997 to 2000. Minntech was a \$75 million per year publicly traded (NASDAQ-MNTX) medical device company offering services for the dialysis, filtration, and separation markets. Prior to employment at Minntech from 1970 to 1997, he held senior marketing, business development and international positions at Medtronic, Cardiac Pacemakers, Inc. and Johnson & Johnson. Mr. McGoldrick is on the Board of Directors of two other start-up medical device companies. We believe Mr. McGoldrick's experience as CEO of a public company and extensive experience in the medical device industry provide valuable insight on our Board.

Andrew P. Reding, Director. Mr. Reding is an executive with extensive experience in sales and marketing of capital equipment for the acute care markets. He has served as a director of the Company since 2006 and he is currently the President and Chief Executive Officer of TRUMPF Medical Systems, Inc., a position he has held since April 2007. Prior to that, he was Director of Sales at Smith & Nephew Endoscopy and prior to that, he served as Vice President of Sales and Director of Marketing with Berchtold Corporation from 1994 to 2006. His experience is in the marketing and sales of architecturally significant products for the operating room, emergency department and the intensive care unit. Mr. Reding has successfully developed high quality indirect and direct sales channels, implemented programs to interface with facility planners and architects and developed GPO and IDN portfolios. Mr. Reding holds a bachelor's degree from Marquette University and an MBA from The University of South Carolina. We believe Mr. Reding's strong experience in sales and marketing of capital equipment to hospital operating rooms provides unique insight into the industry we serve and makes him a valued member of the Board.

Carl Schwartz, Director. Mr. Schwartz was the owner manager of dental groups in Burton, Michigan and Grand Blanc, Michigan. Dr. Schwartz previously served on the Board of Delta Dental Corporation of Michigan, was a member of the Michigan Advisory Board for Liberty Mutual Insurance and was a member of the Board of Trustees of the Museum of Contemporary Art in Florida.

David O. Johnson, Chief Operating Officer. Mr. Johnson has been Chief Operating Officer since July 2012. He was previously the Acting Chief Operating Officer since December 2011 and had been a consultant to medical device companies since October 2010. Mr. Johnson has over 30 years' experience in executive, operations and management positions in rapid growth medical device organizations, directing growth domestically and internationally with products ranging from consumer based disposable commodity items to Class III implantable devices. His experience includes executive management, training, product development, business development, regulatory and quality assurance, operations, supplier development and technology acquisitions. From August 2007 to September 2010 Mr. Johnson was President and CEO of Spring Forest Qigong, an alternative healthcare organization. Prior to August 2007 he had been a co-founder and Vice President of Operations at Epitek, Inc. since January 2005, and prior to that time he was a co-founder and President of Timm Medical Technologies. He also held positions including Vice President-Operations/Technology at UroHealth/Imagyn, Vice-President Operations at Dacomed Corporation and various technical, operations and training positions at American Medical Systems and Pfizer Corporation. He also holds a number of patents in the medical device field and the exercise fitness industry.

Bob Myers, Chief Financial Officer. Effective July 1, 2012, Mr. Myers was appointed as the Chief Financial Officer of the Company. Mr. Myers was the Acting Chief Financial Officer and Corporate Secretary for the Company since December 2011. He has over 30 years' experience in multiple industries focusing on medical device, service and manufacturing and for the past ten years has been a financial contractor represented various contracting firms in the Minneapolis area. He has spent much of his career as a Chief Financial Officer and/or Controller. Mr. Myers was a contract CFO at Disetronic Medical, contract Corporate Controller for Diametric Medical Devices and contract CFO for Cannon Equipment. Previously he held executive positions with American Express, Capitol Distributors, and International Creative Management and was a public accountant with the international firm of Laventhol & Horwath. Mr. Myers has an MBA in Finance from Adelphi University and a BBA in Public Accounting from Hofstra University.

Family Relationships

There are no family relationships among our directors and executive officers.

Audit Committee of the Board; Audit Committee Financial Expert

The Audit Committee of the Board of Directors was established by the Board in accordance with Section 3(a)(58)(A) of the Exchange Act to oversee the Company's corporate accounting and financial reporting processes and audits of its financial statements.

The functions of the Audit Committee include, among other things:

- serving as an independent and objective party to monitor the Company's financial reporting process and internal control system;
- coordinating, reviewing and appraising the audit efforts of the Company's independent auditors and management and, to the extent the Company has an internal auditing or similar department or persons performing the functions of such department ("internal auditing department" or "internal auditors"), the internal auditing department; and
- communicating directly with the independent auditors, financial and senior management, the internal auditing department, and the Board of Directors regarding the matters related to the committee's responsibilities and duties.

Both our independent registered public accounting firm and management periodically meet privately with the Audit Committee.

Our Audit Committee currently consists of Mr. McGoldrick, as the chairperson, Mr. Reding and Mr. Schwartz. Mr. McGoldrick has a strong and vast financial history specializing in the medical device industry. He qualifies as a financial expert and meets independence within the meaning of NASDAQ's listing standards. Each Audit Committee member is a non-employee director of the Board. The Board of Directors reviews the NASDAQ listing standards definition of independence for Audit Committee members on an annual basis and has determined that all current members of our Audit Committee are independent (as independence is currently defined in Rule 5605(a)(2) of the NASDAQ listing standards). The Audit Committee met four times in fiscal 2014 and four times in fiscal 2015.

Director Independence

Under NASDAQ listing standards, a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the board of directors. The Board of Directors consults with our counsel to ensure that the Board of Directors' determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of the NASDAQ, as in effect from time to time.

Consistent with these considerations, after review of all relevant transactions or relationships between each director, or any of his or her family members, and the Company, its senior management, and its independent registered public accounting firm, the Board of Directors has affirmatively determined that the following directors and nominees are independent directors within the meaning of the NASDAQ listing standards: Messrs. McGoldrick, Reding, and Schwartz. In making this determination, the Board of Directors found that none of these directors and nominees had a material or other disqualifying relationship with the Company. Mr. Kornberg, our President and Chief Executive Officer, is not independent by virtue of his managing partnership position with SOK Partners.

Compensation Committee

The Compensation Committee of the Board of Directors currently consists of two directors, Mr. McGoldrick, as the chairperson, and Mr. Schwartz. Both members of the Compensation Committee were appointed by the Board of Directors, and such committee consists entirely of directors who are "outside directors" for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code"), "non-employee directors" for purposes of Rule 16b-3 under the Exchange Act and "independent" as independence is currently defined in Rule 4200(a) (15) of the NASDAQ listing standards. In fiscal 2015, the Compensation Committee met two times. The functions of the Compensation Committee include, among other things:

- approving the annual compensation packages, including base salaries, incentive compensation, deferred compensation and stock-based compensation, for our executive officers;
- administering our stock incentive plans, and subject to Board approval in the case of executive officers, approving grants of stock, stock options and other equity awards under such plans;
- approving the terms of employment agreements for our executive officers;
- developing, recommending, reviewing and administering compensation plans for members of the Board of Directors;
- reviewing and discussing the compensation discussion and analysis with management; and
- preparing any compensation committee report required to be included in the annual proxy statement.

All Compensation Committee approvals regarding compensation to be paid or awarded to our executive officers are rendered with the full power of the Board, though not necessarily reviewed by the full Board.

Our Chief Executive Officer may not be present during any Board or Compensation Committee voting or deliberations with respect to his compensation. Our Chief Executive Officer may, however, be present during any other voting or deliberations regarding compensation of our other executive officers, but may not vote on such items of business.

Compensation Committee Interlocks and Insider Participation

As indicated above, the Compensation Committee consists of Mr. McGoldrick and Mr. Schwartz. No member of the Compensation Committee has ever been an executive officer or employee of ours. None of our officers currently serves, or has served during the last completed year, on the compensation committee or the board of directors of any other entity that has one or more officers serving as a member of the board of directors or the Compensation Committee.

Governance/Nominating Committee

The Governance/Nominating Committee of the Board of Directors currently consists of Mr. McGoldrick, as the chairperson, and Mr. Reding, each of whom is an “independent director,” as such term is defined by The NASDAQ Market Listing Rule 5605(a)(2), and free from any relationship that, in the opinion of the Board, would interfere with the exercise of his or her independent judgment as a member of the Committee.

The members of the Committee are elected annually by the Board. Committee members may be removed for any reason or no reason at the discretion of the Board, and the Board may fill any Committee vacancy that is created by such removal or otherwise. The Committee’s chairperson shall be designated by the full Board or, if it does not do so, the Committee members shall elect a chairperson upon the affirmative vote of a majority of the directors serving on the Committee.

The Committee may form and delegate authority to subcommittees as it may deem appropriate in its sole discretion.

Structure and Meetings

The chairperson of the Committee presides at each meeting and, in consultation with the other members of the Committee, sets the frequency and length of each meeting and the agenda of items to be addressed at each meeting. The chairperson of the Committee ensures that the agenda for each meeting is circulated to each Committee member in advance of the meeting. The Committee reports its actions and recommendations to the Board.

Goals and Responsibilities

In furtherance of its purposes, the Committee:

- Evaluates the composition, organization and governance of the Board, determines future requirements and make recommendations to the Board for approval;
- Determines desired Board and committee skills and attributes and criteria for selecting new directors;
- Reviews candidates for Board membership consistent with the Committee’s criteria for selecting new directors and annually recommend a slate of nominees to the Board for consideration at the Company’s annual stockholders’ meeting;
- Reviews candidates for Board membership, if any, recommended by the Company’s stockholders;
- Conducts the appropriate and necessary inquiries into the backgrounds and qualifications of possible director candidates;
- Evaluates and considers matters relating to the qualifications and retirement of directors;
- Develops a plan for, and consults with the Board regarding, management succession; and
- Advises the Board generally on corporate governance matters.

In addition, the Committee, if and when deemed appropriate by the Board or the Committee, will develop and recommend to the Board a set of corporate governance principles applicable to the Company, and review and reassess the adequacy of such guidelines annually and recommend to the Board any changes deemed appropriate. The Committee also advises the Board on (a) committee member qualifications, (b) appointments, removals and rotation of committee members, (c) committee structure and operations (including authority to delegate to subcommittees), and (d) committee reporting to the Board. Finally, the Committee performs any other activities consistent with this Charter, the Company's Certificate of Incorporation, Bylaws and governing law as the Committee or the Board deems appropriate.

The Committee will review and reassess at least annually the adequacy of the Charter and recommend any proposed changes to the Board for approval.

Committee Resources

The Committee has the authority to obtain advice and seek assistance from internal or external legal, accounting or other advisors. The Committee has the sole authority to retain and terminate any search firm to be used to identify director candidates, including sole authority to approve such search firm's fees and other retention terms.

Diversity

The Board of Directors does not currently have a policy regarding attaining diversity on the Board.

EXECUTIVE COMPENSATION

This section describes the material elements of the compensation awarded to, earned by or paid to our Chief Executive Officer and our two most highly compensated executive officers other than our Chief Executive Officer, as determined in accordance with SEC rules, collectively referred to as the “named executive officers.”

Summary Compensation Table for Fiscal 2015 and 2014

The following table provides information regarding the compensation earned during the fiscal years ended December 31, 2015 and December 31, 2014 by each of the named executive officers:

| Name and Principal Position | Year | (5) Salary | Bonus | Stock Awards | (1) Option Awards | (6) All Other Compensation | Total Compensation |
|--|------|---------------|------------|-----------------|-------------------------|----------------------------------|-----------------------|
| Joshua Kornberg, CEO, President (2) | 2015 | \$ 326,162 | \$ 562,941 | - | \$ 417,628 | \$ 27,000 | \$ 1,333,731 |
| | 2014 | \$ 275,000 | - | - | \$ 428,708 | \$ 33,000 | \$ 736,708 |
| David O. Johnson, COO (3) | 2015 | \$ 180,926 | \$ 178,000 | - | \$ 32,969 | - | \$ 391,895 |
| | 2014 | \$ 180,000 | - | - | \$ 52,910 | - | \$ 232,910 |
| Bob Myers, CFO (4) | 2015 | \$ 174,550 | \$ 130,750 | - | \$ 30,222 | - | \$ 335,522 |
| | 2014 | \$ 165,000 | - | - | \$ 44,087 | - | \$ 209,087 |

- (1) Represents the actual compensation cost recognized during 2015 and 2014 as determined pursuant to FASB ASC 718 – Stock Compensation utilizing the assumptions discussed in Note 3, “Stock Options and Warrants,” in the notes to the financial statements included in this report.
- (2) In 2014 Mr. Kornberg also received options to purchase 2,179 shares of common stock as fees for serving on the Board of Directors. Mr. Kornberg’s minimum bonus for 2015 was 75% of his base salary or \$206,250. During 2015 he also received \$356,691 in additional bonuses, in recognition of bonus amounts from prior years that were waived. In 2015 also received bonus options to purchase 209,126 shares of common stock at \$2.63 per share. Mr. Kornberg also received options to purchase 6,321 shares of common stock as fees for serving on the Board of Directors.
- (3) Mr. Johnson’s minimum bonus for 2015 was 20% of his base salary, or \$36,000. During 2015 he received \$117,000 in income from additional bonuses in recognition of bonus amounts from prior years that were waived and \$25,000 in an unwaived previous year’s bonus. In 2015 he also received bonus options to purchase 17,111 shares of common stock at \$2.63 per share.
- (4) Mr. Myers’s minimum bonus for 2015 was 20% of his base salary, or \$33,000. During 2015 he received \$97,000 in income from additional bonuses in recognition of bonus amounts from prior years that were waived. During 2015 he also received bonus options to purchase 15,685 shares of common stock at \$2.63 per share.
- (5) Salaries shown, where applicable are net of the 401(k) retirement plan put in place during 2013.
- (6) Mr. Kornberg’s All Other Compensation consists of health insurance premiums for Canadian health insurance for 2015 and 2014.

Outstanding Equity Awards at Fiscal Year-end for Fiscal 2015

The following table sets forth certain information regarding outstanding equity awards held by the named executive officers as of December 31, 2015:

| | Grant Date | Number of Securities Underlying Options Exercisable | Number of Securities Underlying Options Unexercisable | Option Exercise Price | Option Expiration Date |
|--------------------|------------|---|---|-----------------------|------------------------|
| Joshua Komberg (1) | 8/13/2012 | 80,000 | | \$ 6.00 | 8/13/2022 |
| | 3/14/2013 | 192,000 | | \$ 5.63 | 3/14/2023 |
| | 9/30/2013 | 210 | | \$ 23.85 | 9/30/2018 |
| | 12/31/2013 | 247 | | \$ 20.25 | 12/31/2018 |
| | 3/6/2014 | 32,609 | | \$ 17.25 | 3/6/2024 |
| | 3/31/2014 | 360 | | \$ 13.88 | 3/31/2024 |
| | 6/30/2014 | 444 | | \$ 11.25 | 6/30/2024 |
| | 9/30/2014 | 606 | | \$ 8.25 | 9/30/2024 |
| | 12/31/2014 | 769 | | \$ 6.50 | 12/31/2024 |
| | 3/31/2015 | 1,449 | | \$ 3.45 | 3/31/2025 |
| | 6/30/2015 | 1,613 | | \$ 3.10 | 6/30/2025 |
| | 9/30/2015 | 1,558 | | \$ 3.21 | 9/30/2025 |
| | 10/21/2015 | 209,126 | | \$ 2.63 | 10/21/2025 |
| 12/31/2015 | 1,701 | | \$ 2.94 | 12/31/2025 | |
| David O. Johnson | 8/13/2012 | 13,334 | | \$ 6.00 | 8/13/2022 |
| | 3/18/2013 | 12,659 | | \$ 5.93 | 3/18/2023 |
| | 3/6/2014 | 4,174 | | \$ 17.25 | 3/6/2024 |
| | 10/21/2015 | 17,111 | | \$ 2.63 | 10/21/2025 |
| Bob Myers | 8/13/2012 | 13,334 | | \$ 6.00 | 8/13/2022 |
| | 3/18/2013 | 10,549 | | \$ 5.93 | 3/18/2023 |
| | 3/6/2014 | 3,479 | | \$ 17.25 | 3/6/2024 |
| | 10/21/2015 | 15,685 | | \$ 2.63 | 10/21/2025 |

- (1) Does not reflect an award of 66,667 shares of restricted stock which the Compensation Committee has approved. Such shares would vest upon certain changes in control of the Company.

Executive Compensation Components for Fiscal 2015

Base Salary. Base salary is an important element of our executive compensation program as it provides executives with a fixed, regular, non-contingent earnings stream to support annual living and other expenses. As a component of total compensation, we generally set base salaries at levels believed to attract and retain an experienced management team that will successfully grow our business and create stockholder value. We also utilize base salaries to reward individual performance and contributions to our overall business objectives, but seek to do so in a manner that does not detract from the executives' incentive to realize additional compensation through our stock options and restricted stock awards.

The Compensation Committee reviews the Chief Executive Officer's salary at least annually. The Compensation Committee may recommend adjustments to the Chief Executive Officer's base salary based upon the Compensation Committee's review of his current base salary, incentive cash compensation and equity-based compensation, as well as his performance and comparative market data. The Compensation Committee also reviews other executives' salaries throughout the year, with input from the Chief Executive Officer. The Compensation Committee may recommend adjustments to other executives' base salary based upon the Chief Executive Officer's recommendation and the reviewed executives' responsibilities, experience and performance, as well as comparative market data.

In utilizing comparative data, the Compensation Committee seeks to recommend salaries for each executive at a level that is appropriate after giving consideration to experience for the relevant position and the executive's performance. The Compensation Committee reviews performance for both our Company (based upon achievement of strategic initiatives) and each individual executive. Based upon these factors, the Compensation Committee may recommend adjustments to base salaries to better align individual compensation with comparative market compensation, to provide merit-based increases based upon individual or company achievement, or to account for changes in roles and responsibilities.

Stock Options and Other Equity Grants. Consistent with our compensation philosophies related to performance-based compensation, long-term stockholder value creation and alignment of executive interests with those of stockholders, we make periodic grants of long-term compensation in the form of stock options or restricted stock to our executive officers, directors and others in the organization.

Stock options provide executive officers with the opportunity to purchase common stock at a price fixed on the grant date regardless of future market price. A stock option becomes valuable only if the common stock price increases above the option exercise price and the holder of the option remains employed during the period required for the option shares to vest. This provides an incentive for an option holder to remain employed by us. In addition, stock options link a significant portion of an employee's compensation to stockholders' interests by providing an incentive to achieve corporate goals and increase stockholder value. Under our Amended and Restated 2012 Stock Incentive Plan (the "2012 Plan"), we may also make grants of restricted stock awards, restricted stock units, performance share awards, performance unit awards and stock appreciation rights to officers and other employees. We adopted the 2012 Plan to give us flexibility in the types of awards that we could grant to our executive officers and other employees.

Limited Perquisites; Other Benefits. We provide our employees with a full complement of employee benefits, including health and dental insurance, short term and long term disability insurance, life insurance, a 401(k) plan, FSA flex plan and Section 125 plan. Mr. Kornberg receives \$3,000 monthly as a health insurance reimbursement in lieu of accepting the Company medical plan benefits.

Employment Contracts

Employment Agreement with Chief Executive Officer

Base Salary. Our employment agreement, dated March 14, 2013, with Joshua Kornberg, President, Chief Executive Officer and Interim Chairman of the Board, provided that his initial annual base salary would be \$250,000 and that his base salary for subsequent years is to be determined by the Board. Effective in March 2014 Mr. Kornberg's annualized base salary was increased to \$275,000. We offered this amount as part of a package of compensation to ensure that we retain Mr. Kornberg in his current capacity with our Company. The compensation package for Mr. Kornberg was designed to provide annual cash compensation, combined with the equity compensation described below, sufficient to induce him to remain with the Company and continue to incentivize him to create revenue growth and stockholder value.

Incentive Compensation. In connection with his employment during the Term, Mr. Kornberg shall be eligible to receive cash and/or equity incentive compensation as determined by the Board and/or the Compensation Committee from time to time, including, without limitation, the incentive compensation described below:

Annual Bonus. Mr. Komberg shall be eligible to receive with respect to each calendar year ending during the Term of the Executive's employment with the Company a bonus payment subject to the terms of this Section (the "Annual Bonus"). The amount of the Annual Bonus shall be determined based on the attainment of reasonable Company and/or individual performance metrics established and revised annually by the Compensation Committee and/or Board in consultation with Mr. Komberg, which shall be set at or about the beginning of the given year to which the metrics relate. Mr. Komberg's target Annual Bonus shall be 150% of his Base Salary (the "Target Annual Bonus"); provided, however, that the actual amount of the Annual Bonus for each calendar year shall be determined by the Compensation Committee and/or the Board based on relative level of achievement of the applicable metrics and which may be in an amount greater or less than the Target Annual Bonus but shall not be less than 50% of the Target Annual Bonus (the "Minimum Bonus"). The Annual Bonus shall be payable in a single lump sum in cash between January 1 and March 15 of the year following the calendar year to which such Annual Bonus relates. Except as otherwise provided in this Agreement, to earn and be entitled to payment of an Annual Bonus in respect of a given calendar year, Mr. Komberg must be employed by the Company on the last day (*i.e.*, December 31st) of the calendar year to which the bonus relates. Notwithstanding the foregoing, Mr. Komberg (or his estate, if applicable) shall receive a pro-rata portion of the Target Annual Bonus (calculated as if all applicable performance metrics had been attained at 100% and based on the portion of the calendar year during which the Executive was employed) (the "Pro-Rata Bonus") for the calendar year during which the Executive's employment terminates due to: (i) termination by the Company without Cause (as defined below); (ii) termination by the Executive for Good Reason (as defined below); or (iii) termination due to the Executive's death or Disability (as defined below).

Equity Incentive Grants. Mr. Komberg shall receive annual equity incentive grants (*e.g.*, stock options, restricted stock or other stock-based awards) with respect to each calendar year ending during the Term of Mr. Komberg's employment with the Company, which shall be granted on December 31st of the calendar year to which such grant pertains (each an "Annual Grant"). Each Annual Grant shall be granted in accordance with the terms and conditions of the applicable equity incentive plan or plans then in effect and will be evidenced by an award agreement issued under the applicable plan. The target aggregate grant date fair value of each such Annual Grant shall be 200% of Mr. Komberg's Base Salary (the "Target Grant"); provided, however, that the actual amount of any such award shall be determined in the reasonable discretion of the Compensation Committee and/or the Board and may be greater than the Target Grant but shall not be less than the Target Grant. Each Annual Grant shall be fully vested on the date of grant; provided, however, that any equity incentive grant Mr. Komberg receives that is not an Annual Grant will be subject to the vesting provisions contained in the applicable award agreement.

Compensation Upon Termination.

Termination Generally. If Mr. Komberg's employment with the Company is terminated for any reason, the Company shall pay or provide to Mr. Komberg (or to his authorized representative or estate) (i) any Base Salary earned through the Date of Termination (paid on or before the time required by law but in no event more than 30 days after the Date of Termination); (ii) if the Date of Termination occurs following the end of a given calendar year, but prior to payment of the Annual Bonus with respect to such year, the Annual Bonus payable for such prior calendar year (paid in accordance with Section 2(c)(i) of the Employment Contract; (iii) if applicable under Section 2(c)(i), the Pro-Rata Bonus for the year during which the Date of Termination occurs (paid at the time the Company pays bonuses with respect to such year); (iv) unpaid expense reimbursements (subject to, and in accordance with, Sections 2(d), 2(f) and 2(i) of the Employment Contract) and, if applicable under Section 2(h) of the Employment Contract, unused vacation that accrued through the Date of Termination (paid on or before the time required by law but in no event more than 30 days after the Date of Termination); and (v) any vested benefits the Executive may have under any Executive Benefit Plan or other employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such benefit plans (collectively, the "Accrued Benefits").

Termination by the Company Without Cause or by the Executive with Good Reason. During the Term, if Mr. Komberg's employment is terminated by the Company without Cause as provided in Section 3(d) of the Employment Contract or Mr. Komberg terminates his employment for Good Reason as provided in Section 3(e), then the Company shall pay Mr. Komberg his Accrued Benefits (as provided in Section 4(a) of the Employment Contract). In addition, subject to Mr. Komberg signing a full and final release of all releasable claims in favor of the Company and related persons and entities in a reasonable form and manner reasonably satisfactory to the Company (the "Release") and the expiration of the applicable revocation period for the Release:

- a. the Company shall pay Mr. Komberg an amount equal to two (2) times the sum of (x) the Executive's Base Salary; and (y) the Executive's Target Annual Bonus (*i.e.*, 100% of the Target Annual Bonus amount as if employed for the full year and all applicable performance metrics had been fully achieved) (the "Severance Amount"). The Severance Amount shall be paid in a cash lump sum payment within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the lump sum payment of the Severance Amount shall be paid in the second calendar year (but prior to the end of the 60-day period). Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulations Section 1.409A-2(b)(2);

- b. effective upon the Date of Termination, all stock options and other stock-based awards (including, without limitation, all such awards/grants under Sections 2(b)(ii) and 2(c)(ii)) of the Employment Contract held by Mr. Kornberg and all yet unvested portions thereof shall immediately and fully accelerate and vest and become exercisable or nonforfeitable as of the Date of Termination (to the extent that the Release is not effective as of the Date of Termination, the Company shall take all necessary corporate action to ensure that no such stock-based awards terminate or are forfeited by Mr. Kornberg from the Date of Termination until the date such accelerated vesting and/or exercisability becomes effective);
- c. if the Annual Grant had not been made with respect to the year in which the Date of Termination occurs, the Company shall grant to Mr. Kornberg on the Date of Termination such number of shares of common stock with an aggregate fair market value on the Date of Termination equal to 200% of Mr. Kornberg's Base Salary (which grant shall be fully vested on the Date of Termination); and
- d. the Company shall provide Mr. Kornberg (and, as applicable, his spouse and eligible dependents) with continued medical (health, dental, and vision), life insurance (as provided in Section 2(g) of the Employment Contract) and disability benefits, at the Company's expense, to the same extent in which the Executive participated prior to the Date of Termination for a period of 18 months following the Date of Termination; provided, however, if the Company cannot provide, for any reason, Mr. Kornberg or his dependents with the opportunity to participate in the benefits to be provided pursuant to this paragraph (at the Company's expense), the Company shall pay to Mr. Kornberg a single sum cash payment, payable within 60 days following the date the Company cannot provide such benefits, in an amount equal to the fair market value of the benefits to be provided pursuant to this paragraph plus an amount necessary to "gross-up" Mr. Kornberg with respect to any Federal, state or local taxation due on such single sum cash payment. If Mr. Kornberg (and his spouse and dependents, as applicable) was/were covered by Mr. Kornberg's own health insurance premiums for which Mr. Kornberg was being reimbursed pursuant to Section 2(t) of the Employment Contract, then the Company shall pay to Mr. Kornberg a single sum cash payment, payable within 60 days following the Date of Termination, equal to the total amount of the monthly premiums for such insurance coverage for a period of 18 months.

Change in Control Payment. The provisions of this set forth certain terms of an agreement reached between Mr. Kornberg and the Company regarding Mr. Kornberg's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance Mr. Kornberg's continued attention and dedication to his assigned duties and his objectivity during the pendency and/or after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4 of the Employment Contract regarding severance pay and benefits upon a termination of employment by the Company without Cause as provided in Section 3(d) of the Employment Contract, if such termination of employment occurs in connection with or within 18 months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning eighteen (18) months after the occurrence of a Change in Control if Mr. Kornberg remains employed with the Company through and at such time.

Change in Control. In the event of a Change in Control (as defined below):

- a. notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all stock options and other stock-based awards held by Mr. Kornberg (including, without limitation, all such awards/grants under Sections 2(b)(ii) and 2(c)(ii) of the Employment Contract and all yet unvested portions thereof shall immediately and fully accelerate and vest and become fully exercisable or nonforfeitable as of immediately prior to the closing or occurrence (as applicable) of the event constituting the Change in Control; and
- b. if, in connection with or within 18 months after a Change in Control, Mr. Kornberg's employment is terminated by the Company without Cause as provided in Section 3(d) of the Employment Contract or Mr. Kornberg terminates his employment for any reason, then the Company shall pay Mr. Kornberg his Accrued Benefits (as provided in Section 4(a) above). In addition, subject to the signing of the Release by the Executive and the expiration of the applicable revocation period for the Release:

- (A) the Company shall pay Mr. Komberg a lump sum in cash in an amount equal to three times the sum of (A) Mr. Komberg's current Base Salary (or the Executive's Base Salary in effect immediately prior to the Change in Control, if higher); and (B) Mr. Komberg's Target Annual Bonus (or Mr. Komberg's Target Annual Bonus in effect immediately prior to the Change in Control, if higher). Such payment shall be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid in the second calendar year (but prior to the end of the 60-day period);
- (B) to the extent not covered by and accelerated pursuant to Section 5(a)(i) of the Employment Contract, effective upon the Date of Termination all stock options and other stock-based awards (including, without limitation, all such awards/grants under Sections 2(b)(ii) and 2(c)(ii)) of the Employment Contract held by Mr. Komberg and all yet unvested portions thereof shall immediately and fully accelerate and vest and become exercisable or nonforfeitable as of the Date of Termination (to the extent that the Release is not effective as of the Date of Termination, the Company shall take all necessary corporate action to ensure that no such stock-based awards terminate or are forfeited by Mr. Komberg from the Date of Termination until the date such accelerated vesting and/or exercisability becomes effective);
- (C) if the Annual Grant had not been made with respect to the year in which the Date of Termination occurs, the Company shall grant to Mr. Komberg on the Date of Termination such number of shares of common stock with an aggregate fair market value on the Date of Termination equal to 200% of Mr. Komberg's Base Salary (which grant shall be fully vested on the Date of Termination);
- (D) the Company shall provide Mr. Komberg (and, as applicable, his spouse and eligible dependents) with continued medical (health, dental, and vision), life insurance (as provided in Section 2(g) of the Employment Contract) and disability benefits, at the Company's expense, to the same extent in which Mr. Komberg participated prior to the Date of Termination for a period of 18 months following the Date of Termination; provided, however, if the Company cannot provide, for any reason, Mr. Komberg or his dependents with the opportunity to participate in the benefits to be provided pursuant to this paragraph (at the Company's expense), the Company shall pay to Mr. Komberg a single sum cash payment, payable within 60 days following the date the Company cannot provide such benefits, in an amount equal to the fair market value of the benefits to be provided pursuant to this paragraph plus an amount necessary to "gross-up" Mr. Komberg with respect to any Federal, state or local taxation due on such single sum cash payment. If Mr. Komberg (and his spouse and dependents, as applicable) was/were covered by Mr. Komberg's own health insurance premiums for which Mr. Komberg was being reimbursed pursuant to Section 2(f) of the Employment Contract, then the Company shall pay to Mr. Komberg a single sum cash payment, payable within 60 days following the Date of Termination, equal to the total amount of the monthly premiums for such insurance coverage for a period of 18 months;
- (E) Gross-Up Payment.
- (i) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that the amount of any compensation, payment or distribution by the Company to or for the benefit of Mr. Komberg, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and the applicable regulations thereunder (the "Severance Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, or any interest or penalties are incurred by Mr. Komberg with respect to such excise tax (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), then Mr. Komberg shall be entitled to receive an additional payment or payments (collectively, the "Gross-Up Payment") such that the net amount retained by Mr. Komberg, after deduction of any Excise Tax on the Severance Payments, any Federal, state, and local income tax, employment tax and Excise Tax upon the payment provided by this Section, and any interest and/or penalties assessed with respect to such Excise Tax, shall be equal to the Severance Payments.

- (ii) Subject to the provisions of Section 5(b)(iii) of the Employment Contract, all determinations required to be made under this clause (ii), including whether a Gross-Up Payment is required and the amount of such Gross-Up Payment, shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and Mr. Kornberg within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or Mr. Kornberg. For purposes of determining the amount of the Gross-Up Payment, Mr. Kornberg shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the Gross-Up Payment is to be made, and state and local income taxes at the highest marginal rates of individual taxation in the state and locality of Mr. Kornberg's residence on the Date of Termination, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes. The Gross-Up Payment, if any, as determined pursuant to this clause (ii), shall be paid to the relevant tax authorities as withholding taxes on behalf of Mr. Kornberg at such time or times when each Excise Tax payment is due. Any determination by the Accounting Firm shall be binding upon the Company and Mr. Kornberg. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments which will not have been made by the Company should have been made (an "Underpayment"). In the event that the Company exhausts its remedies pursuant to Section 5(b)(iii) of the Employment Contract and Mr. Kornberg thereafter is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred, consistent with the calculations required to be made hereunder, and any such Underpayment, and any interest and penalties imposed on the Underpayment and required to be paid by Mr. Kornberg in connection with the proceedings described in Section 5(b)(iii) of the Employment Contract, shall be promptly paid by the Company to the relevant tax authorities as withholding taxes on behalf of Mr. Kornberg.
- (iii) Mr. Kornberg shall notify the Company in writing of any claim by the Internal Revenue Service that, if successful, would require the payment by the Company of the Gross-up Payment. Such notification shall be given as soon as practicable but no later than ten business days after Mr. Kornberg knows of such claim and shall apprise the Company of the nature of such claim and the date on which such claim is requested to be paid. Mr. Kornberg shall not pay such claim prior to the expiration of the 30-day period following the date on which he gives such notice to the Company (or such shorter period ending on the date that any payment of taxes with respect to such claim is due). If the Company notifies Mr. Kornberg in writing prior to the expiration of such period that it desires to contest such claim, provided that the Company has set aside adequate reserves to cover the Underpayment and any interest and penalties thereon that may accrue, the Executive shall:
- (A) give the Company any information reasonably requested by the Company relating to such claim;
 - (B) take such action in connection with contesting such claim as the Company shall reasonably request in writing from time to time, including, without limitation, accepting legal representation with respect to such claim by an attorney selected by the Company;
 - (C) cooperate with the Company in good faith in order to effectively contest such claim; and
 - (D) permit the Company to participate in any proceedings relating to such claim; provided, however, that the Company shall bear and pay directly all costs and expenses (including additional interest and penalties) incurred in connection with such contest and shall indemnify and hold Mr. Kornberg harmless, on an after-tax basis, for any Excise Tax or income tax, including interest and penalties with respect thereto, imposed as a result of such representation and payment of costs and expenses.

- (iv) If, after a Gross-Up Payment by the Company on behalf of Mr. Kornberg pursuant to this Section 5(b) of the Employment Contract, Mr. Kornberg becomes entitled to receive any refund with respect to such claim, Mr. Kornberg shall (subject to the Company's complying with the requirements of Section 5(b)(iii) of the Employment Contract) promptly pay to the Company the amount of such refund (together with any interest paid or credited thereon after taxes applicable thereto).

Definitions. For purposes of Section 5 of the Employment Contract, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

- (i) there is consummated a merger, consolidation, statutory exchange or reorganization, unless securities representing more than 50% of the total combined voting power of the outstanding voting securities of the successor corporation are immediately thereafter beneficially owned directly or indirectly and in substantially the same proportion, by the persons who beneficially owned the Company's outstanding voting securities immediately prior to such transaction;
- (ii) any transaction or series of related transactions pursuant to which any person or any group of persons comprising a "group" within the meaning of Rule 13d-5(b)(1) under the Securities Exchange Act of 1934, as amended (other than the Company or a person that, prior to such transaction or series of related transactions, directly or indirectly, is controlled by or is under common control with the Company), becomes directly or indirectly the beneficial owner (within the meaning of Rule 13d-3 of the Securities Exchange Act of 1934, as amended) of securities possessing (or convertible into or exercisable for securities possessing) 30% or more of the total combined voting power of the securities (determined by the power to vote with respect to the elections of Board members) outstanding immediately after the consummation of such transaction or series of related transactions, whether such transaction involves a direct issuance from the Company or the acquisition of outstanding securities held by one or more of the Company's stockholders;
- (iii) there is consummated a sale, lease, exclusive license, or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license, or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than 50% of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale, lease, license, or other disposition; or
- (iv) individuals who, on the Effective Date, are members of the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new director was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new director shall, for purposes of sentence, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (ii) solely as the result of (A) the acquisition of additional securities by Dr. Samuel Herschkowitz, Joshua Kornberg or their affiliates; or (B) a repurchase or other acquisition of securities by the Company which, by reducing the number of shares of voting securities outstanding, increases the proportionate number of voting securities beneficially owned by any person to 30% or more of the combined voting power of all of the then outstanding voting securities; provided, however, that if any person referred to in this clause (B) shall thereafter become the beneficial owner of any additional shares of voting securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 30% or more of the combined voting power of all of the then outstanding voting securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (ii).

Employment Agreements with Chief Operating Officer and Chief Financial Officer

On August 13, 2012, the Company entered into employment agreements with David O. Johnson, who has served as Chief Operating Officer since July 1, 2012, and Bob Myers, who has served as Chief Financial Officer since July 1, 2012 (Messrs. Johnson and Myers are referred to as the “executives”). Under the agreements the employment of each of these individuals with the Company is at will.

The annualized base salaries of Messrs. Johnson and Myers were \$150,000 and \$125,000, respectively for their first year employed. Effective July 1, 2013 the annualized base salaries of Messrs. Johnson and Myers were \$180,000 and \$150,000, respectively. Effective in March 2014 Mr. Myers annualized base salary was increased to \$165,000. Such base salaries may be adjusted by the Company but may not be reduced except in connection with a reduction imposed on substantially all employees as part of a general reduction. The executives will also each be eligible to receive an annual incentive bonus for each calendar year at the end of which he remains employed by the Company, subject to the attainment of certain objectives. The executives have a minimum bonus guarantee of 20% of their annualized salary.

If the Company terminates the executive’s employment without cause or if the executive terminates his employment for “good reason,” he shall be entitled to receive from Company severance pay in an amount equal to (a) before the first anniversary of the date of the agreement, three months of base salary, or (b) on or after the first anniversary of the date of the agreement, twelve months of base salary, in either case less applicable taxes and withholdings. In that event, he will receive a bonus payment on a pro-rata basis through the date of termination and any accrued, unused vacation pay. The severance pay, bonus payment, and other consideration are conditioned upon executive’s execution of a full and final release of liability. “Cause” is defined to mean the executive engages in willful misconduct or fails to follow the reasonable and lawful instructions of the Board, if such conduct is not cured within 30 days after notice; the executive embezzles or misappropriates assets of Company or any of its subsidiaries; the executive’s violation of his obligations in the agreement, if such conduct is not cured within 30 days after notice; breach of any agreement between the executive and the Company or to which Company and the executive are parties, or a breach of his fiduciary responsibility to the Company; commission by of fraud or other willful conduct that adversely affects the business or reputation of Company; or, Company has a reasonable belief the executive engaged in some form of harassment or other improper conduct prohibited by Company policy or the law. “Good reason” is defined as (i) a material diminution in Employee’s position, duties, base salary, and responsibilities; or (ii) Company’s notice to Employee that his or her position will be relocated to an office which is greater than 100 miles from Employee’s prior office location. In all cases of Good Reason, Employee must have given notice to Company that an alleged Good Reason event has occurred and the circumstances must remain uncorrected by Company after the expiration of 30 days after receipt by Company of such notice.

During each executive’s employment with the Company and for twelve months thereafter, regardless of the reason for the termination, he will not engage in a competing business, as defined in the agreement and will not solicit any person to leave employment with the Company or solicit clients or prospective clients of the Company with whom he worked, solicited, marketed, or obtained confidential information about during his employment with the Company, regarding services or products that are competitive with any of the Company’s services or products.

Potential Payments Upon Termination or Change of Control

Most of our stock option agreements provide for an acceleration of vesting in the event of a change in control as defined in the 2012 Stock Incentive Plan. See also “Employment Contracts” above.

Most of our stock option agreements provide for an acceleration of vesting in the event of a change in control as defined in the agreements and in the 2012 Stock Incentive Plan. Additionally, the restricted stock agreements that were awarded to management and directors in 2013 also provide for an acceleration of vesting in the event there is a change in control as defined in the 2012 Plan. See also “Employment Contracts” above.

Director Compensation

Effective in 2013 the Board instituted a quarterly and an annual stock options award program for all the directors under which they will be awarded options to purchase \$5,000 worth of shares of common stock, par value \$0.01 per quarter at an exercise price determined by the close on the last day of the quarter. Additionally, the directors that serve on a committee will receive options to purchase \$10,000 worth of shares of common stock, par value \$0.01 annually, per committee served, at an exercise price determined by the close on the last day of the year.

Director Compensation Table for Fiscal 2015

The following table summarizes the compensation paid to each non-employee director in the fiscal year ended December 31, 2015:

| | Fees Paid or Earned in Cash | Stock Awards | Option Awards | Total |
|-----------------------|--------------------------------|--------------|------------------|-----------|
| Thomas McGoldrick | \$ - | \$ - | \$ 36,759(1) | \$ 36,759 |
| Ricardo Koenigsberger | \$ - | \$ - | \$ 7,340(2) | \$ 7,340 |
| Andrew Reding | \$ - | \$ - | \$ 29,402(3) | \$ 29,402 |
| Frank Mancuso, Jr. | \$ - | \$ - | \$ 29,402(4) | \$ 29,402 |

- (1) Mr. McGoldrick was awarded options to purchase 16,525 shares of common stock both for serving on the Board and for participating on the Audit, Compensation and Corporate Governance Committees.
- (2) Mr. Koenigsberger was awarded options to purchase 3,062 shares of common stock both for serving on the Board and for participating on the Audit and Corporate Governance Committees. Mr. Koenigsberger resigned as a Director effective June 5, 2015.
- (3) Mr. Reding was awarded options to purchase 13,124 shares of common stock both for serving on the Board and for participating on the Audit and Corporate Governance Committees.
- (4) Mr. Mancuso was awarded options to purchase 13,124 shares of common stock both for serving on the Board and for participating on the Audit and Compensation Committees. Mr. Mancuso resigned as a Director effective January 13, 2016.

Equity Compensation Plan Information

The following table presents the equity compensation plan information as of December 31, 2015:

| | Number of securities to be issued upon exercise of outstanding restricted stock, warrants and options (a) | Weighted- average exercise price of outstanding options, warrants (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c) |
|--|---|--|---|
| Equity compensation plans approved by security holders (1) | 850,385 | \$ 5.33 | 534,293 |
| Equity compensation plans not approved by security holders | - | \$ - | - |

- (1) Consists of outstanding options under the 2008 Equity Incentive Plan and the 2012 Stock Incentive Plan. The remaining share authorization under the 2008 Equity Incentive Plan was rolled over to the current 2012 Stock Incentive Plan.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The Audit Committee has the responsibility to review and approve all transactions to which a related party and the Company may be a party prior to their implementation, to assess whether such transactions meet applicable legal requirements.

In connection with the sale of the Series A Preferred Shares on February 4, 2014, Joshua Kornberg, our President, Chief Executive Officer and Interim Chairman of the Board, was one of the purchasers. Mr. Kornberg purchased 19,231 Series A Preferred Shares for a purchase price of \$25,000 and received warrants to purchase 52 shares of common stock.

SOK Partners, LLC (“SOK”), a significant stockholder with Mr. Kornberg and Dr. Samuel Herschkowitz as managing partners, invested in the July 2014 offering of convertible notes and warrants. In November 2014, the convertible noteholders agreed to convert certain balances of the convertible notes in connection with the public offering of the Existing Units, in consideration of the agreement to issue certain additional shares. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Historical Financing — 2014 Sales of Convertible Notes and Warrants.” In connection with the Unit Offering in August 2015, all such convertible notes were redeemed at a redemption price of 140% of the principal amount thereof, plus accrued and unpaid interest. The Company paid approximately \$163,000 to SOK in redemption of its convertible note.

In connection with the Unit Exchange that was consummated on August 31, 2015, 250 shares of Series A Convertible Stock held by Mr. Kornberg were exchanged for 2,778 Exchange Units.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL HOLDERS AND MANAGEMENT

The following table sets forth as of March 11, 2016 certain information regarding beneficial ownership of our common stock by:

- Each person known to us to beneficially own 5% or more of our common stock;
- Each of our executive officers who in this prospectus are collectively referred to as the “named executive officers;”
- Each of our directors; and
- All of our executive officers (as that term is defined under the rules and regulations of the SEC) and directors as a group.

We have determined beneficial ownership in accordance with Rule 13d-3 under the Exchange Act. Beneficial ownership generally means having sole or shared voting or investment power with respect to securities. Unless otherwise indicated in the footnotes to the table, each stockholder named in the table has sole voting and investment power with respect to the shares of common stock set forth opposite the stockholder’s name. We have based our calculation of the percentage of beneficial ownership on 39,498,125 shares of the Company’s common stock outstanding on March 11, 2016. Unless otherwise noted below, the address for each person or entity listed in the table is c/o Skyline Medical Inc., 2915 Commers Drive, Suite 900, Eagan, Minnesota 55121.

| Name of Beneficial Owner | Amount and Nature of Beneficial Ownership | Percent of Class |
|--|--|------------------------|
| Officers and Directors | | |
| Josh Komberg ⁽²⁾ | 1,995,506 | 5.0% |
| David Johnson ⁽³⁾ | 47,338 | 0.1% |
| Bob Myers ⁽⁴⁾ | 43,178 | 0.1% |
| Thomas J. McGoldrick ⁽⁵⁾ | 22,619 | *% |
| Andrew Reding ⁽⁶⁾ | 18,013 | *% |
| Carl Schwartz ⁽¹⁰⁾ | 1,725,375 | 4.4% |
| All directors and executive officers as a group (6 persons) | 3,852,029 | 9.8% |
| 5% Security Holders | | |
| Sam Herschkowitz ⁽⁹⁾ | 1,995,506 | 5.1% |
| SOK Partners ⁽⁸⁾ | 1,995,506 | 5.1% |
| APA, SOK, Sam Herschkowitz, Josh Komberg | 1,995,506 | 5.0% |
| APA ⁽⁷⁾ | 1,995,506 | 5.0% |

* Under 0.1%

- (1) Under Rule 13d-3, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (i) voting power, which includes the power to vote, or to direct the voting of shares; and (ii) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in this table does not necessarily reflect the person's actual ownership or voting power with respect to the number of shares of common stock actually outstanding.
- (2) Includes (i) 4,183 shares owned directly, (ii) 519,433 shares issuable upon exercise of options that are exercisable within 60 days of March 11, 2016, (iii) 1,025 shares issuable upon exercise of warrants, (iv) 821,023 shares owned directly by SOK Partners, (v) 10,862 shares issuable upon conversion of a convertible note held by SOK Partners, (vi) 6,312 shares issuable upon exercise of warrants held by SOK Partners, (vii) 630,322 shares owned directly by APA, and (viii) 15,041 shares held directly by Dr. Herschkowitz. Mr. Kornberg and Dr. Samuel Herschkowitz are the managing partners of SOK Partners and APA. Upon the consummation of the Unit Offering, 250 shares of Series A Convertible Preferred Stock held by Mr. Kornberg were exchanged for 2,778 Exchange Units.
- (3) Includes options to purchase 47,338 shares that are exercisable within 60 days of March 11, 2016.
- (4) Includes options to purchase 43,178 shares that are exercisable within 60 days of March 11, 2016.
- (5) Includes options to purchase 9,133 shares that are exercisable within 60 days of March 11, 2016.
- (6) Includes options to purchase 8,195 shares that are exercisable within 60 days of March 11, 2016.
- (7) Includes (i) 630,322 shares owned directly, (ii) 821,023 shares owned directly by SOK Partners, (iii) 10,862 shares issuable upon conversion of a convertible note held by SOK Partners, (iv) 6,312 shares issuable upon exercise of warrants held by SOK Partners, (v) 4,183 shares held directly by Mr. Kornberg, and (vi) 15,041 shares held directly by Dr. Herschkowitz. Mr. Kornberg and Dr. Samuel Herschkowitz are the managing partners of SOK Partners and APA. Upon the consummation of the Unit Offering, 250 shares of Series A Convertible Preferred Stock held by Mr. Kornberg were exchanged for 2,778 Exchange Units.
- (8) Includes (i) 821,023 shares owned directly, (ii) 10,862 shares issuable upon conversion of a convertible note, (iii) 6,312 shares issuable upon exercise of warrants held by SOK Partners, (iv) 15,041 shares held directly by Dr. Herschkowitz, (v) 4,183 shares held directly by Mr. Kornberg, (vi) 519,433 shares issuable upon exercise of options held by Mr. Kornberg that are exercisable within 60 days of March 11, 2016, (vii) 1,025 shares issuable upon exercise of warrants held by Mr. Kornberg, and (viii) 6 shares owned directly by APA. Mr. Kornberg and Dr. Samuel Herschkowitz are the managing partners of SOK Partners and APA. Upon the consummation of the Unit Offering, 250 shares of Series A Convertible Preferred Stock held by Mr. Kornberg were exchanged for 2,778 Exchange Units.
- (9) Includes (i) 15,041 shares owned directly, (ii) 821,023 shares owned directly by SOK Partners, (iii) 10,862 shares issuable upon conversion of a convertible note held by SOK Partners, (iv) 6,312 shares issuable upon exercise of warrants held by SOK Partners, (v) 4,183 shares held directly by Mr. Kornberg, (vi) 519,433 shares issuable upon exercise of options held by Mr. Kornberg that are exercisable within 60 days of March 11, 2016, (vii) 1,025 shares issuable upon exercise of warrants held by Mr. Kornberg, (viii) 630,322 shares owned directly by APA. Mr. Kornberg and Dr. Samuel Herschkowitz are the managing partners of SOK Partners and APA. Upon the consummation of the Offering, 250 shares of Series A Convertible Preferred Stock held by Mr. Kornberg were exchanged for 2,778 Exchange Units.
- (10) Includes (i) 1,618,201 shares owned directly, (ii) 36,111 shares of Series B Convertible Preferred Stock, (iii) 56,381 shares issuable upon exercise of warrants held by Dr. Schwartz that are exercisable within 60 days of March 11, 2016, and (iv) 14,682 shares issuable upon exercise of options held by Dr. Schwartz that are exercisable within 60 days of March 11, 2016.

GENERAL TERMS OF THE EXCHANGE OFFER

Purpose of the Exchange Offer

We believe that the variable number of shares currently issuable upon a cashless exercise of Series A Warrants creates significant market uncertainty and downward pressure on the market value of our common stock. The purpose of the Exchange Offer is to replace as many Series A Warrants as possible with Series B Warrants, which feature a fixed number of shares issuable upon a cashless exercise. We believe this exchange will create more certainty and transparency in the market for our common stock and our capital structure, which we believe will benefit our stockholders.

Terms of the Exchange Offer

Upon the terms and subject to the conditions described in this prospectus and in the Letter of Transmittal, we are offering to issue up to an aggregate of 32,203,297 Series B Warrants to the holders of outstanding Series A Warrants who validly tender their Series A Warrants on or prior to the Expiration Date. All outstanding Series A Warrants that are (i) not tendered prior to the Expiration Date; or (ii) tendered but withdrawn any time before the Expiration Date or, for any valid reason, not accepted by us, will continue to be outstanding according to their terms unmodified.

As of March 16, 2016, there were outstanding 3,157,186 Series A Warrants subject to the Exchange Offer. This prospectus and the Letter of Transmittal are being sent to all registered holders of the outstanding Series A Warrants. There will be no fixed record date for determining registered holders of the outstanding Series A Warrants entitled to participate in the Exchange Offer. The Series A Warrants that were issued to former holders of shares of our Series A Preferred Stock as a component of certain units in exchange for such shares may participate in the Exchange Offer.

The Exchange Agent will act as agent for the tendering holders of the Series A Warrants for the purposes of receiving (i) the Series B Warrants and (ii) the completed, signed and dated Letter of Transmittal and other required documents. We will issue the Series B Warrants promptly after the Expiration Date.

We intend to conduct the Exchange Offer in accordance with the applicable requirements of the Securities Act and the Exchange Act, and the rules and regulations promulgated by the SEC thereunder.

Market and Trading Information

The Series A Warrants are not listed for trading on any market. Our shares of common stock are traded on NASDAQ under the symbol "SKLN." The last reported sale price of our shares of common stock on March 16, 2016 was \$0.21 per share.

Expiration Date

The Exchange Offer will expire on the Expiration Date, which is at midnight, Eastern time, on April 21, 2016 unless extended by us at our sole discretion.

Extensions, Termination or Amendment

Subject to applicable law, we expressly reserve the right, at any time or at various times, and regardless of whether any events preventing satisfaction of the conditions to the Exchange Offer, to extend the period of time during which the Exchange Offer is open by giving oral (to be confirmed in writing) or written notice of such extension to the Exchange Agent and by making public disclosure by press release or other appropriate means of such extension to the extent required by law.

During any extension of the Exchange Offer, all Series A Warrants previously tendered and not accepted by us will remain subject to the Exchange Offer and may, subject to the terms and conditions of the Exchange Offer, be accepted by us, and all Series A Warrants previously tendered and accepted by us pursuant to the Exchange Offer will remain effective. In addition, we may waive conditions without extending the Exchange Offer in accordance with applicable law.

If any of the conditions described below under “— Conditions to the Exchange Offer” have not been satisfied with respect to the Exchange Offer, we reserve the right, at our sole discretion:

- to extend the Exchange Offer,
- to delay accepting any Series A Warrants tendered pursuant to the Exchange Offer,
- to terminate the Exchange Offer, or
- to otherwise amend the Exchange Offer in any respect in compliance with applicable securities laws and stock exchange rules.

Announcements

If the conditions to the Exchange Offer are satisfied, or if we waive all of the conditions that have not been satisfied, we will accept, on the Expiration Date and after we receive completed and duly executed Letters of Transmittal or Agent’s Messages (as defined below) with respect to any and all of the Series A Warrants tendered at such time, the tendered Series A Warrants by notifying the Exchange Agent of our acceptance. The notice may be oral if we promptly confirm it in writing.

Acceptance of Tendered Series A Warrants Pursuant to the Exchange Offer

If the conditions to the Exchange Offer are satisfied, or if we waive all of the conditions that have not been satisfied, we will accept, on the Expiration Date and after we receive completed and duly executed letters of transmittal or Agent’s Messages (as defined below) with respect to any and all of the Series A Warrants tendered at such time, the tendered Series A Warrants by notifying the Exchange Agent of our acceptance. The notice may be oral if we promptly confirm it in writing.

An “Agent’s Message” is a message transmitted by The Depository Trust Company (“DTC”), received by the Exchange Agent and forming part of the timely confirmation of a book entry transfer (“Book-Entry Confirmation”), which states that DTC has received an express acknowledgement from you that you have received this prospectus and agree to be bound by the terms of the Letter of Transmittal, and that we may enforce such agreement against you.

We expressly reserve the right, in our sole discretion, to delay acceptance of the Series A Warrants tendered pursuant to the Exchange Offer, or to terminate the Exchange Offer and not accept the Series A Warrants tendered pursuant to the Exchange Offer, (1) if any of the conditions to the Exchange Offer shall not have been satisfied or validly waived by us, or (2) in order to comply in whole or in part with any applicable law.

In all cases, the Series B Warrants will be issued only after timely receipt by the Exchange Agent of (1) Book-Entry Confirmation of the Series B Warrants into the Exchange Agent’s account at DTC, (2) the properly completed and duly executed Letter of Transmittal (or a facsimile thereof) or an Agent’s Message in lieu thereof, and (3) any other documents required by the Letter of Transmittal.

For purposes of the Exchange Offer, we will have accepted the Series A Warrants tendered pursuant to the Exchange Offer, if, as and when we give oral or written notice to the Exchange Agent of our acceptance of such Series A Warrants pursuant to the Exchange Offer. In all cases, the issuance of the Series B Warrants will be made by the deposit of such consideration with the Exchange Agent, which will act as your agent for the purposes of receiving such consideration from us, and delivering such consideration to you.

If, for any reason whatsoever, acceptance of any Series A Warrants tendered or the issuance of the Series B Warrants is delayed or we extend the Exchange Offer or are unable to accept the tender of the Series A Warrants pursuant to the Exchange Offer, then, without prejudice to our rights set forth herein, we may instruct the Exchange Agent to retain the Series A Warrants tendered and such tender may not be withdrawn, subject to the limited circumstances described in “— Withdrawal of Tender and Participation in this Exchange Offer” below.

We will have the right, which may be waived, to reject the defective tender of Series A Warrants pursuant to the Exchange Offer as invalid and ineffective. If we waive our rights to reject a defective tender, subject to the other terms and conditions set forth in the Exchange Offer and the Letter of Transmittal, you will be entitled to the Series B Warrants.

We will pay or cause to be paid all transfer taxes with respect to the tender of the Series A Warrants pursuant to the Exchange Offer unless the box titled "Special Issuance Instructions" or the box titled "Special Delivery Instructions" on the Letter of Transmittal has been completed, as described in the instructions thereto.

Procedures for Participating in the Exchange Offer

General

In order to participate in the Exchange Offer, you must tender your Series A Warrants as described below. It is your responsibility to tender your Series A Warrants. We have the right to waive any defects. However, we are not required to waive defects and are not required to notify you of defects in your tender.

If you have any questions or need help in tendering your Series A Warrants pursuant to the Exchange Offer, please contact the Exchange Agent whose address and telephone number is listed below under "— Depository and the Exchange Agent."

The method of tendering the Series A Warrants and delivering the Letters of Transmittal and other required documents is at your election and risk. If delivery is by mail, we recommend that registered mail, properly insured, with return receipt requested, be used. In all cases, sufficient time should be allowed to assure timely delivery. No Series A Warrants, Letters of Transmittal or other required documents should be sent to the Company, the Dealer-Manager or the Information Agent.

Proper Participation in the Exchange

All Series A Warrants are currently held in book-entry form through DTC. Except as set forth below with respect to DTC's automated tender offer program procedures, for a holder of Series A Warrants to tender their Series A Warrants pursuant to the Exchange Offer, the Series A Warrants and a properly completed and duly executed Letter of Transmittal (or a facsimile thereof), together with any signature guarantees and any other documents required by the Instructions to the Letter of Transmittal, or an Agent's Message in lieu thereof, must be received by the Exchange Agent in accordance with the wire instructions specified in the Letter of Transmittal and at the address or facsimile number set forth on the back cover of this prospectus prior to the Expiration Date.

In all cases, the issuance of the Series B Warrants pursuant to the Exchange Offer will be made only after timely receipt by the Exchange Agent of:

- a Book-Entry Confirmation with respect to the tender of Series A Warrants;
- the Letter of Transmittal (or a facsimile thereof) properly completed and duly executed, or an Agent's Message in lieu thereof; and
- any required signature guarantees and other documents required by the Letter of Transmittal.

Book-Entry Transfer

The Exchange Agent has or will establish an account with respect to the Series A Warrants at DTC for purposes of the Exchange Offer, and any financial institution that is a participant in the DTC system and whose name appears on a security position listing as the record owner of the Series A Warrants may make book-entry delivery of Series A Warrants by causing DTC to transfer the Series A Warrants into the Exchange Agent's account at DTC in accordance with DTC's procedure for transfer. Although delivery of Series A Warrants may be effected through book-entry transfer into the Exchange Agent's account at DTC, either an Agent's Message or a Letter of Transmittal (or a facsimile thereof) properly completed and duly executed, along with any required signature guarantees and any other required documents, must be transmitted to and received by the Exchange Agent in accordance with the wire instructions specified in the Letter of Transmittal and at one of the addresses set forth on the back cover of this prospectus prior to the Expiration Date.

Tender of Series A Warrants and Participation in the Exchange Offer Through DTC's Automated Tender Offer Program

In lieu of physically completing and signing the Letter of Transmittal and delivering it to the Exchange Agent, DTC participants may electronically transmit their acceptance of the Exchange Offer through DTC's automated tender offer program, for which the transaction will be eligible. In accordance with DTC's automated tender offer program procedures, DTC will then verify the acceptance of the Exchange Offer and send an Agent's Message to the Exchange Agent for its acceptance.

If a holder of Series A Warrants transmits its acceptance through DTC's automated tender offer program, delivery of such Series A Warrants must be made to the Exchange Agent pursuant to the book-entry delivery procedures set forth herein. Unless such holder of Series A Warrants tenders Series A Warrants by book-entry delivery, we may, at our option, treat such exercise as defective for purposes of acceptance and the right to receive the Series B Warrants pursuant to the Exchange Offer. Delivery of documents to DTC (physically or by electronic means) does not constitute delivery to the Exchange Agent. If you desire to tender Series A Warrants prior to the Expiration Date, you must allow sufficient time for completion of the DTC's automated tender offer program procedures during the normal business hours of DTC on such date.

Procedures for Tendering Series A Warrants Held Through a Custodian

If you are a beneficial owner of Series A Warrants, but the holder of such Series A Warrants is a custodial entity such as a bank, broker, dealer, trust company or other nominee, and you seek to tender your Series A Warrants pursuant to the Exchange Offer, you must provide appropriate instructions to such holder of the Series A Warrants in order to tender through DTC's automated tender offer program with respect to such Series A Warrants. Beneficial owners may be instructed to complete and deliver an instruction letter to such holder of Series A Warrants for this purpose. We urge you to contact such person that holds Series A Warrants for you if you wish to tender your Series A Warrants pursuant to the Exchange Offer.

Signature Guarantees

Signatures on all Letters of Transmittal must be guaranteed by a recognized participant in the Securities Transfer Agents Medallion Program (a "Medallion Signature Guarantor"), unless the Letter of Transmittal is delivered, and any tendered Series A Warrants thereby are delivered (i) by a registered holder of Series A Warrants (or by a participant in DTC whose name appears on a security position listing as the owner of such Series A Warrants) who has not completed either the box entitled "Special Delivery Instructions" or "Special Issuance Instructions" on the Letter of Transmittal or (ii) for the account of a member firm of a registered national securities exchange, a member of the Financial Industry Regulatory Authority or a commercial bank or trust company having an office or correspondent in the United States (each of the foregoing being referred to as an "Eligible Institution"). If the Series A Warrants are registered in the name of a person other than the signer of the Letter of Transmittal, or if Series A Warrants not accepted for exercise pursuant to the Exchange Offer are to be returned to a person other than such holder of Series A Warrants, then the signatures on the Letters of Transmittal accompanying the delivery of the Series A Warrants must be guaranteed by a Medallion Signature Guarantor as described above.

Determination of Validity of Tender of Series A Warrants

All questions as to the validity, form, eligibility (including time of receipt) and acceptance of any tendered Series A Warrants pursuant to this Exchange Offer and any of the procedures described above, and the form and validity (including time of receipt of notices of withdrawal) of all documents will be determined by us in our sole discretion, which determination will be final and binding, subject to the rights of our Series A Warrant holders to challenge such determination in a court of competent jurisdiction. We reserve the absolute right to reject any or all tenders of Series A Warrants determined by us not to be in proper form, or if the acceptance of or tender of Series A Warrants may, in the opinion of our counsel, be unlawful. We also reserve the right to waive any conditions to the Exchange Offer that we are legally permitted to waive.

Your tender of Series A Warrants pursuant to the Exchange Offer will not be deemed to have been made until all defects or irregularities in your exercise have been cured or waived. Neither we, the Exchange Agent nor any other person or entity is under any duty to give notification of any defects or irregularities in any exercise or withdrawal of any exercise pursuant to the Exchange Offer, or will incur any liability for failure to give any such notification.

Please do not send Letters of Transmittal to us, the Dealer Manager or the Information Agent. You should send Letters of Transmittal only to the Exchange Agent, at its office as indicated under “General Terms of the Exchange Offer—Depository and Exchange Agent” in this prospectus and in the Letter of Transmittal. The Exchange Agent can answer your questions regarding how to tender your Series A Warrants.

Withdrawal of Tender and Participation in this Exchange Offer

Your right to withdraw the tender of any Series A Warrants pursuant to the Exchange Offer will expire at the Expiration Date.

To be effective, a written or facsimile transmission notice of withdrawal of a tender of Series A Warrants or a properly transmitted “Request Message” through DTC’s automated tender offer program system must:

- be received by the Exchange Agent at one of the addresses specified on the back cover of this prospectus prior to the Expiration Date;
- specify the name of the holder of the tendered Series A Warrants to be withdrawn;
- contain the description of the Series A Warrants to be withdrawn; and
- be signed by the holder of the Series A Warrants in the same manner as the original signature on the Letter of Transmittal or be accompanied by documents of transfer sufficient to have the trustee register the transfer of the Series A Warrants into the name of the person withdrawing the tender of such Series A Warrants.

If the tendered Series A Warrants to be withdrawn have been delivered or otherwise identified to the Exchange Agent, a signed notice of withdrawal is effective immediately upon receipt by the Exchange Agent of written or facsimile transmission of the notice of withdrawal or revocation (or receipt of a Request Message) even if physical release is not yet effected. A withdrawal of tendered Series A Warrants can only be accomplished in accordance with the foregoing procedures.

If you withdraw tendered Series A Warrants, you will have the right to re-tender such Series A Warrants on or prior to the Expiration Date in accordance with the procedures described above for tendering Series A Warrants. If we amend or modify the terms of the Exchange Offer, or the information concerning the Exchange Offer, in a manner determined by us to constitute a material change to the holders of the Series A Warrants, we will disseminate additional Exchange Offer materials and extend the period of the Exchange Offer, including any withdrawal rights, to the extent required by law and as we determine necessary. An extension of the Expiration Date will not affect a holder of Series A Warrant’s withdrawal rights.

Return of Series A Warrants

If we do not accept any Series A Warrants in the Exchange Offer for any reason described in the terms and conditions of the Exchange Offer or if a greater number of Series A Warrants are tendered than the holder of the Series A Warrants desires to tender and exchange in the Exchange Offer or if the Series A Warrants so tendered are withdrawn pursuant to the terms of the Exchange Offer, we will return such Series A Warrants without expense to the holder. In the case of Series A Warrants that are tendered by book-entry transfer into the Exchange Offer's account at DTC according to the procedures described below, such Series A Warrants will be credited to an account maintained with DTC. These actions will occur as promptly as practicable after the expiration or termination of the Exchange Offer.

Your Representations to Us

By signing or agreeing to be bound by the Letter of Transmittal and other required documents, you will represent to us that, among other things:

- any Series B Warrants that you receive will be acquired in the ordinary course of your business;
- you have no arrangement or understanding with any person to participate in the distribution of the Series B Warrants;
- if you are not a broker-dealer, you are not engaged in and do not intend to engage in the distribution of the Series B Warrants; and
- if you are a broker-dealer, that you will receive Series B Warrants for your own account in exchange for the tender of the Series A Warrants that were acquired as a result of market-making activities or other trading activities and that you will deliver a prospectus in connection with any resale of the components of the Series B Warrants.

Interests of Certain Persons in the Exchange Offer

Joshua Komberg, our President, Chief Executive Officer and Interim Chairman of the Board, holds 11,112 Series A Warrants. See "Background and Purpose of the Exchange Offer—Exchange Units." Mr. Komberg intends to tender all of his Series A Warrants for Series B Warrants in the Exchange Offer. Other than Mr. Komberg, none of our officers or directors or their respective affiliates beneficially owns any of the Exchange Units and, therefore, will not participate in the Exchange Offer.

Resales

Each broker-dealer that receives Series B Warrants for its own account in exchange for the tender of Series A Warrants, where such Series A Warrants were acquired by such broker-dealer as a result of market-making activities or other trading activities, must acknowledge that it will deliver a prospectus in connection with any resale of the components of the Series B Warrants. See "Plan of Distribution."

Conditions to the Exchange Offer

Notwithstanding any other provisions of the Exchange Offer, we will not be required to accept the tendered Series A Warrants pursuant to the Exchange Offer or to issue the Series B Warrants pursuant to the Exchange Offer, and may terminate, amend or extend the Exchange Offer or delay issuing the Series B Warrants, if any of the following shall occur or exist or have not been satisfied, or have not been waived by us, prior to the Expiration Date:

- no action or event shall have occurred, no action shall have been taken, and no statute, rule, regulation, judgment, order, stay, decree or injunction shall have been promulgated, enacted, entered or enforced applicable to the Exchange Offer or the exchange of Series A Warrants for Series B Warrants under the Exchange Offer by or before any court or governmental regulatory or administrative agency, authority or tribunal of competent jurisdiction, including, without limitation, taxing authorities, that challenges the making of the Exchange Offer or the exchange of Series A Warrants for Series B Warrants under the Exchange Offer or would reasonably be expected to, directly or indirectly, prohibit, prevent, restrict or delay consummation of, or would reasonably be expected to otherwise adversely affect in any material manner, the Exchange Offer or the exchange of Series A Warrants for Series B Warrants under the Exchange Offer;

- there shall not have occurred:
 - o any general suspension of or limitation on trading in securities on The NASDAQ Capital Market, whether or not mandatory,
 - o a declaration of a banking moratorium or any suspension of payments in respect of banks by federal or state authorities in the United States, whether or not mandatory,
 - o a commencement of a war, armed hostilities, a terrorist act or other national or international calamity directly or indirectly relating to the United States, or
 - o in the case of any of the foregoing existing at the time of the commencement of the Exchange Offer, a material acceleration or worsening thereof; and
- the SEC shall have declared our registration statement on Form S-4 of which this prospectus forms a part effective, and such registration statement shall not be subject to a stop order, and no proceedings for that purpose shall have been instituted or be pending or, to our knowledge, be contemplated or threatened by the SEC.

These conditions are for our benefit and may be asserted by us or may be waived by us, including any action or inaction by us giving rise to any condition, in whole or in part, at any time and from time to time at or prior to the Expiration Date, in our reasonable discretion. We may additionally terminate the Exchange Offer if any condition is not satisfied on or prior to the Expiration Date. If any of these events occur, subject to the termination rights described above, we may (i) return any tendered Series A Warrants to you, (ii) extend the Exchange Offer and retain all tendered Series A Warrants until the expiration of the extended Exchange Offer, or (iii) amend the Exchange Offer in any respect by giving oral or written notice of such amendment to the Exchange Agent and making public disclosure of such amendment to the extent required by law. Notwithstanding the foregoing, in no event may we terminate, amend or extend the Exchange Offer or delay issuing the Series B Warrants if the occurrence, existence or nonsatisfaction of any of the foregoing resulted from our action or failure to act.

We have not made a decision as to what circumstances would lead us to waive any condition, and any such waiver would depend on circumstances prevailing at the time of such waiver. Although we have no present plans or arrangements to do so, we reserve the right to amend, at any time, the terms of the Exchange Offer. We will give holders of Series A Warrants notice of such amendments as may be required by applicable law.

Dealer Manager

We have retained Source Capital Group, Inc. to act as dealer manager (the “Dealer Manager”) for the Exchange Offer.

We will pay the Dealer Manager customary fees for its services in connection with the Exchange Offer and will also reimburse the Dealer Manager for certain out-of-pocket expenses, including certain fees and expenses of its legal counsel incurred in connection with the Exchange Offer. The Dealer Manager’s fee will be calculated based on the value of the Series A Warrants tendered. Such fee structure provides that the Dealer Manager will receive an aggregate fee equal to 3% of the dollar value of any Series A Warrants exchanged for Series B Warrants. The obligations of the Dealer Manager are subject to certain conditions. We have agreed to indemnify the Dealer Manager against certain liabilities, including liabilities under the federal securities laws, or to contribute to payments that the Dealer Manager may be required to make in respect thereof.

From time to time, the Dealer Manager has provided, and may in the future provide, investment banking, commercial banking, financial advisory and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees and other compensation.

Fees and Expenses

We will bear the expenses of soliciting the tender of the Series A Warrants pursuant to the Exchange Offer. The principal solicitation is being made by mail; however, we may make additional solicitation by facsimile, email, telephone or in person by our officers and regular employees and those of our affiliates.

We will pay the Dealer Manager, the Information Agent and the Exchange Agent reasonable and customary fees for their services and reimburse them for their related reasonable out-of-pocket expenses. We may also pay brokerage houses and other custodians, nominees and fiduciaries the reasonable out-of-pocket expenses incurred by them in forwarding copies of this prospectus, Letter of Transmittal and related documents to the beneficial owners of the Series A Warrants and in handling or forwarding Series A Warrants tendered pursuant to the Exchange Offer.

We will pay cash expenses to be incurred in connection with the Exchange Offer. They include:

- SEC registration fees for the Series B Warrants,
- fees and expenses of the Exchange Agent and the Depositary,
- accounting, advisory and legal fees,
- printing costs, and
- related fees and expenses.

If your Series A Warrants are held or will be held through a broker or other nominee on your behalf, your broker or other nominee may charge you a commission for doing so.

Transfer Taxes

If you tender your Series A Warrants pursuant to the Exchange Offer, you will not be required to pay any transfer taxes. We will pay all transfer taxes, if any, applicable to the tender of Series A Warrants in the Exchange Offer. The tendering holder will, however, be required to pay any transfer taxes, whether imposed on the registered holder or any other person, if:

- certificates representing the Series B Warrants issued in exchange for the Series A Warrants are to be delivered to, or are to be issued in the name of, any person other than the registered holder of the Series A Warrants tendered,
- tendered Series A Warrants are registered in the name of any person other than the person signing the Letter of Transmittal, or
- a transfer tax is imposed for any reason other than the issuance of Series B Warrants in exchange for the tender of Series A Warrants in the Exchange Offer.

If satisfactory evidence of payment of any transfer taxes payable by an exercising holder is not submitted with the Letter of Transmittal, the amount of the transfer taxes will be billed directly to that exercising holder. The Exchange Agent will retain possession of the Series B Warrants with a value equal to the amount of the transfer taxes due until it receives payment of the taxes.

Consequences of Failure to Participate in the Exchange Offer

If you currently hold Series A Warrants and do not tender them pursuant to the Exchange Offer, then, following the expiration of the Exchange Offer, your Series A Warrants will continue to be outstanding according to their terms unmodified. If you do not participate in this Exchange Offer, you will retain the Series A Warrants. Among other consequences, you will continue to hold warrants that feature a fluctuating number of shares issuable upon a cashless exercise.

Other

Participation in the Exchange Offer is voluntary, and you should carefully consider whether to accept. You are urged to consult your financial, legal, and tax advisors in making your decision on what action to take.

In the future, we may at our discretion seek to acquire untendered Series A Warrants in open market or privately negotiated transactions, through subsequent exchange offers or otherwise. We have no present plan to acquire any Series A Warrants that do not participate in the Exchange Offer.

Depository and Exchange Agent

We have appointed Corporate Stock Transfer, Inc. as the Depository and the Exchange Agent for the Exchange Offer (referred to throughout this prospectus as the "Exchange Agent"). You should direct questions, requests for assistance, and requested for additional copies of the prospectus and the Letter of Transmittal that may accompany this prospectus to the Exchange Agent addressed as follows:

Corporate Stock Transfer, Inc.
3200 Cherry Creek South Drive, Suite 430
Denver, CO 80209

Series A Warrant holders and banks and brokerage firms, please call:
Toll Free: 877-309-2764
Main Phone: 303-282-5800

Deliver to an address other than set forth above will not constitute a valid delivery.

**DESCRIPTION OF SERIES B WARRANTS
INCLUDED IN THE EXCHANGE OFFER**

This description is intended to be an overview of the material provisions of the Series B Warrants. Since this description is only a summary, you should refer to the form of Series B Warrant for a complete description of our obligations and your rights.

Each Series B Warrant entitles the registered holder to receive upon cashless exercise one share of our common stock. The Series B Exchange Warrants are exercisable for a period commencing on the date of issuance and ending on December 31, 2020. The terms of the Series B Warrants are similar to those of the existing Series A Warrants, except that the Series B Warrants do not have a cash exercise feature.

The shares of common stock issuable on exercise of the Series B Warrants are duly authorized and will be, when issued, delivered and paid for in accordance with the Series B Warrants, validly issued and fully paid and non-assessable. We will authorize and reserve at least that number of shares of common stock equal to the number of shares of common stock issuable upon exercise or exchange of all outstanding Series B Warrants.

The Series B Warrants will not be exercisable or exchangeable by the holder of such warrants to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company. For purposes of the limitation described in this paragraph, beneficial ownership and all determinations and calculations are determined in accordance with Section 13(d) of the Exchange Act and the rule and regulations promulgated thereunder.

In addition to (but not duplicative of) the adjustments to the exercise price and the number of shares of common stock issuable upon exercise of the Series B Warrants in the event of stock dividends, stock splits, reorganizations or similar events, if the Company, at any time prior to the three year anniversary of the issuance date:

- declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to all or substantially all of the holders of shares of common stock (a "Distribution"), at any time after the issuance date, then, in each such case, the holders of the Series B Warrants will be entitled to participate in such Distribution to the same extent that the holders would have participated therein if the holder had held the number of shares of common stock acquirable upon complete exercise of the Series B Warrants by paying the exercise price for such shares of common stock in cash in full, as of the date immediately preceding the date on which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of common stock are to be determined for the participation in such Distribution; or
- grants, issues or sells any options, convertible securities or rights to purchase stock, warrants, securities or other property pro rata to all or substantially all of the record holders of any class of shares of common stock (the "Purchase Rights"),

then the holders of Series B Warrants will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon complete exercise of the Series B Warrant by paying the exercise price for such shares of common stock in cash in full, as of the date immediately preceding the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of common stock are to be determined for the grant, issue or sale of such Purchase Rights.

If, at any time a Series B Warrant is outstanding, we consummate any fundamental transaction, as described in the Series B Warrants and generally including any consolidation or merger into another corporation, or the sale of all or substantially all of our assets, or other transaction in which our common stock is converted into or exchanged for other securities or other consideration, the holder of any Series B Warrants will thereafter receive, the securities or other consideration to which a holder of the number of shares of common stock then deliverable upon the exercise or exchange of such Series B Warrants would have been entitled upon such consolidation or merger or other transaction.

The Series B Warrants will be issued in book-entry form under a warrant agent agreement between Corporate Stock Transfer, Inc., as warrant agent, and us, and were initially represented by one or more book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

THE HOLDER OF A SERIES B WARRANT WILL NOT POSSESS ANY RIGHTS AS A STOCKHOLDER UNDER THAT SERIES B WARRANT UNTIL THE HOLDER EXERCISES THE SERIES B WARRANT.

DESCRIPTION OF SECURITIES

The following information describes our capital stock and provisions of our certificate of incorporation and our bylaws. This description is only a summary. You should also refer to our certificate of incorporation and bylaws, each as amended, that have been incorporated by reference or filed with the SEC as exhibits to the registration statement on Form S-4 of which this prospectus forms a part.

General

We are authorized to issue 100,000,000 shares of common stock, par value \$0.01 per share, and 20,000,000 shares of preferred stock, of which 2,300,000 shares are authorized as Series B Convertible Preferred Stock, par value \$0.01 per share.

Common Stock

As of March 11, 2016, we had 39,498,125 shares of common stock issued and outstanding and held by approximately 145 stockholders of record.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders, provided that no proxy shall be voted if executed more than three years prior to the date of the stockholders' meeting except if such proxy provides for a longer period. Holders of our common stock do not have cumulative voting rights.

The holders of common stock are entitled to receive ratably any dividends that may be declared from time to time by our board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities. The common stock has no preemptive or conversion rights or other subscription rights and there are no redemption provisions applicable to our common stock. All outstanding shares of common stock are fully paid and non-assessable, and the shares of common stock offered in this Exchange Offer will be fully paid and not liable for further call or assessment.

Except for directors, who are elected by receiving the highest number of affirmative votes of the shares entitled to be voted for them, or as otherwise required by Delaware law, and subject to the rights of the holders of preferred stock then outstanding (if any), all stockholder action is taken by the vote of a majority of the issued and outstanding shares of common stock present at a meeting of stockholders at which a quorum consisting of a majority of the issued and outstanding shares of common stock is present in person or proxy. In the absence of a quorum for the transaction of business, any meeting may be adjourned from time to time. The stockholders present at a duly called or held meeting may continue to do business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum. Our Chairman of the Board or, in his absence, any other director designated from time to time by the board of directors, shall preside at all meetings of stockholders.

Preferred Stock

Our Board of Directors has the authority, without action by our stockholders, to designate and issue up to 20,000,000 shares of preferred stock in one or more series or classes and to designate the rights, preferences and privileges of each series or class, which may be greater than the rights of our common stock. The Board's authority to issue preferred stock without stockholder approval could make it more difficult for a third party to acquire control of our company, and could discourage such attempt.

Series A Convertible Preferred Stock

On January 24, 2014, the board filed the Certificate of Designation with the Delaware Secretary of State, designating 40,000 shares of preferred stock as the Company's Series A Convertible Preferred Stock. On February 4, 2014, the Company entered into a Securities Purchase Agreement with certain investors pursuant to which the Company agreed to offer and sell 20,550 shares of Series A Convertible Preferred Stock, par value \$0.01 per share (the "Series A Preferred Shares"), in addition to warrants to purchase shares of the Company's common stock. On August 4, 2014, the Company issued additional warrants to such investors, which was required because the Company's common stock was not listed on NASDAQ within 180 days of the closing of the offering of the Series A Preferred Shares.

In connection with the offering of Units that closed on August 31, 2015, the Company agreed with holders of all of its outstanding Series A Preferred Shares for Exchange Units in the Unit Exchange. Upon effectiveness of the Unit Exchange, the Series A Preferred Shares were cancelled and resumed the status of authorized but unissued shares of preferred stock.

Description of Exchange Units

In connection with the Unit Offering, the Company agreed with holders of all of its outstanding Series A Convertible Preferred Stock, par value \$0.01 per share, with a stated value of \$100 per share (the "Series A Preferred Shares") to exchange all of the Series A Preferred Shares for units with the same terms as the Units sold in the Unit Offering (the "Exchange Units"). In the exchange of Series A Preferred Shares for Units, for every dollar of stated value of Series A Preferred Shares tendered the holders received an equivalent value of Exchange Units based on the public offering price of the Units (the "Unit Exchange"). The Unit Exchange was consummated currently with the consummation of the Unit Offering. Upon effectiveness of the Unit Exchange, the Series A Preferred Shares were cancelled and resumed the status of authorized but unissued shares of preferred stock.

Description of Securities Sold in Public Offering of Units

Units

On August 31, 2015, the Company closed an underwritten public offering of 1,666,667 Units (the "Units"), each consisting of one share of our common stock, one share of our Series B Convertible Preferred Stock and four Series A Warrants. Each share of Series B Convertible Preferred Stock is convertible at the option of the holder into one share of our common stock. Each Series A Warrant is exercisable into one share of our common stock at an exercise price of \$4.95 per share. The public offering price for the Units was \$9.00 per Unit and the purchase price for Dawson James Securities, Inc., which served as the underwriter (the "Underwriter") in the offering of Units was \$8.28 per Unit, resulting in an underwriting discount and commission of \$0.72 (or 8.00%) per Unit and total net proceeds to the Company before expenses of \$13.8 million. The Company granted the Underwriter an option for a period of 45 days to purchase up to an additional 250,000 Units solely to cover over-allotments. The Underwriter chose not to purchase any additional Units under the over-allotment option. The Company agreed to issue to the Underwriter a unit purchase option (the "Unit Purchase Option") more fully described below. The Company also agreed to pay the Underwriter a non-accountable expense allowance equal to 1% of the gross proceeds of the Offering (excluding any proceeds from the over-allotment option, if any), as well as to reimburse expenses incurred by the Underwriter of up to \$70,000. The underwritten public offering of Units is referred to in this prospectus as the Unit Offering.

2015 Unit Offering

On August 31, 2015, the Company completed a public offering of 1,666,667 Units (the "Units") as described below. The public offering price in the Offering was \$9.00 per Unit, and the purchase price for the underwriter of the Offering (the "Underwriter") was \$8.28 per Unit, resulting in an underwriting discount and commission of \$0.72 (or 8.00%) per Unit and total net proceeds to the Company before expenses of \$13.8 million. The Company had granted the Underwriter an option for a period of 45 days to purchase up to an additional 250,000 Units solely to cover over-allotments. The Underwriter chose not to purchase any additional Units under the over-allotment option. The Company paid to the Underwriter a non-accountable expense allowance equal to 1% of the gross proceeds of the Offering and agreed to reimburse expenses incurred by the Underwriter up to \$70,000. On August 31, 2015, as a result of the consummation of the Offering and the issuance of the 228,343 Exchange Units in the Unit Exchange described below, the Company issued a total of 1,895,010 Units, comprised of a total of aggregate of 1,895,010 shares of Common Stock, 1,895,010 shares of Series B Preferred Stock and 7,580,040 Series A Warrants.

Each Unit consisted of one share of common stock, par value \$0.01 per share, one share of Series B Convertible Preferred Stock and four Series A Warrants. The shares of Common Stock, the shares of Series B Preferred Stock and the Series A Warrants that comprise the Units automatically separated on February 29, 2016.

Separation of the Units

The shares of our common stock, the shares of Series B Convertible Preferred Stock and the Series A Warrants that comprise the Units will automatically separate on February 29, 2016. However, the shares of our common stock, the shares of the Series B Convertible Preferred Stock and the Series A Warrants will become separable prior to February 29, 2016 if at any time after September 30, 2015 either (i) the closing price of our common stock on the NASDAQ Capital Market is greater than 200% of the Series A Warrants exercise price for a period of 20 consecutive trading days (the "Trading Separation Trigger"), (ii) all Series A Warrants in a given Unit are exercised for cash (solely with respect to the Units that include the exercised Series A Warrants) (a "Warrant Cash Exercise Trigger") or (iii) the Units are delisted (the "Delisting Trigger") from the NASDAQ Capital Market for any reason (any such event, a "Separation Trigger Event"). Upon the occurrence of a Separation Trigger Event, the Units will separate: (i) 15 days after the date of the Trading Separation Trigger, (ii) on the date of any Warrant Cash Exercise Trigger (solely with respect to the Units that include the exercised Series A Warrants) or (iii) on the date of the Delisting Trigger, as the case may be. We refer to the separation of the Units prior to February 29, 2016 as an Early Separation.

Series B Convertible Preferred Stock Included in the Units

In connection with the Unit offering, we issued as part of the Units 1,895,010 shares of Series B Convertible Preferred Stock pursuant to a Certificate of Designation approved by our Board. The Series B Convertible Preferred Stock separated from the Series A Warrants and the Common Stock included within the Units as described above and are currently convertible. The number of shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. Each share of Series B Convertible Preferred Stock will be convertible into one share of common stock on February 29, 2016, or on the date of an Early Separation.

In addition, upon the occurrence of a "Fundamental Transaction", each share of Series B Convertible Preferred Stock shall be automatically converted into one share of common stock of the Company, subject to the beneficial ownership limitation discussed in the next paragraph. A "Fundamental Transaction" means that (i) the Company shall, directly or indirectly, in one or more related transactions, (1) consolidate or merge with or into (whether or not the Company is the surviving corporation) any other person unless the shareholders of the Company immediately prior to such consolidation or merger continue to hold more than 50% of the outstanding shares of voting stock after such consolidation or merger, or (2) sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of the properties and assets of the Company and its subsidiaries, taken as a whole, to any other person, or (3) allow any other person to make a purchase, tender or exchange offer that is accepted by the holders of more than 50% of the outstanding shares of voting stock of the Company (not including any shares of voting stock of the Company held by the person or persons making or party to, or associated or affiliated with the persons making or party to, such purchase, tender or exchange offer), or (4) consummate a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with any other person whereby such other person acquires more than 50% of the outstanding shares of voting stock of the Company (not including any shares of voting stock of the Company held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination), or (ii) any "person" or "group" (as these terms are used for purposes of Sections 13(d) and 14(d) of the Exchange Act and the rules and regulations promulgated thereunder), other than a Permitted Holder, is or shall become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 50% of the aggregate ordinary voting power represented by issued and outstanding voting stock of the Company. The term Permitted Holders means Josh Komberg, Atlantic Partners Alliance and SOK Partners, LLC and each of their respective affiliates.

The Series B Convertible Preferred Stock is not be convertible by the holder of such preferred stock to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company. For purposes of the limitation described in this paragraph, beneficial ownership and all determinations and calculations are determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder.

The Series B Convertible Preferred Stock has no voting rights, except that the holders of shares of a majority of the Series B Convertible Preferred Stock will be required to effect or validate any amendment, alteration or repeal of any of the provisions of the Certificate of Designation that materially adversely affects the powers, preferences or special rights of the Series B Convertible Preferred Stock, whether by merger or consolidation or otherwise; *provided, however,* that (i) in the event of an amendment to terms of the Series B Convertible Preferred Stock, including by merger or consolidation, so long as the Series B Convertible Preferred Stock remains outstanding with the terms thereof materially unchanged, or the Series B Convertible Preferred Stock is converted into, preference securities of the surviving entity, or its ultimate parent, with such powers, preferences or special rights that are, in the good faith determination of the Board of the Company, taken as a whole, not materially less favorable to the holders of the Series B Convertible Preferred Stock than the powers, preferences or special rights of the Series B Convertible Preferred Stock in effect prior to such amendment or the occurrence of such event, taken as a whole, then such amendment or the occurrence of such event will not be deemed to materially and adversely affect such powers, preferences or special rights of the Series B Convertible Preferred Stock and (ii) the authorization, establishment or issuance by the Corporation of any other series of preferred stock with powers, preferences or special rights that are senior to or on a parity with the Series B Preferred Stock, including, but not limited to, powers, preferences or special rights with respect to dividends, distributions or liquidation preferences, shall not be deemed to materially and adversely affect the power, preferences or special rights of the Series B Preferred Stock, and in the case of either clause (i) or (ii), the holders shall not have any voting rights with respect thereto, *and provided further that,* (iii) prior to the date that is the six month anniversary of the Issuance Date, no amendment, alteration or repeal of any of the provisions of this Certificate of Designation shall be made that affects the powers, preferences or special rights of the Series B Preferred Stock in any manner, whether by merger or consolidation or otherwise. An amendment to the terms of the Series B Convertible Preferred Stock only requires the vote of the holders of Series B Convertible Preferred Stock.

With respect to payment of dividends and distribution of assets upon liquidation or dissolution or winding up of the Company, the Series B Convertible Preferred Stock shall rank equal to the common stock of the Company. No sinking fund has been established for the retirement or redemption of the Series B Convertible Preferred Stock. As such, the Series B Convertible Preferred Stock is not subject to any restriction on the repurchase or redemption of shares by the Company due to an arrearage in the payment of dividends or sinking fund installments.

The Series B Convertible Preferred Stock also has no liquidation rights or preemption rights, and there are no special classifications of our Board related to the Series B Convertible Preferred Stock.

The shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock have been duly authorized, validly issued and fully paid and are non-assessable. We have authorized and reserved at least that number of shares of common stock equal to the number of shares of common stock issuable upon conversion of all outstanding Series B Convertible Preferred Stock.

THE HOLDER OF SERIES B CONVERTIBLE PREFERRED STOCK DO NOT POSSESS ANY RIGHTS AS A STOCKHOLDER UNDER THE SHARES OF SERIES B CONVERTIBLE PREFERRED STOCK UNTIL THE HOLDER CONVERTS THE SHARES OF SERIES B CONVERTIBLE PREFERRED STOCK.

There is no established public trading market for our Series B Convertible Preferred Stock, and we do not expect a market to develop. We do not intend to apply to list Series B Convertible Preferred Stock on any securities exchange. Without an active market, the liquidity of the Series B Convertible Preferred Stock will be limited.

Series A Warrants Included in the Units

In connection with the Unit Offering we issued as part of the Units 7,580,040 Series A Warrants to purchase shares of our common stock. The Series A Warrants separated from the Series B Convertible Preferred Stock and the Common Stock included within the Units as described above and are currently exercisable. The Series A Warrants will terminate on August 31, 2020. Each Series A Warrant is exercisable into one share of Common Stock at an initial cash exercise price of \$4.95 per share. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Common Stock and the exercise price.

Holders may exercise Series A Warrants by paying the exercise price in cash or, in lieu of payment of the exercise price in cash, by electing to receive a number of shares of Common Stock equal to the Black Scholes Value (as defined below) based upon the number of shares the holder elects to exercise. The number of shares of Common Stock to be delivered will be determined according to the following formula, referred to as the “Cashless Exercise.”

$$\text{Total Shares} = (A \times B) / C$$

Where:

- Total Shares is the number of shares of common stock to be issued upon a Cashless Exercise
- A is the total number of shares with respect to which the Series A Warrant is then being exercised.
- B is the Black Scholes Value (as defined below).
- C is the closing bid price of our common stock as of two trading days prior to the time of such exercise, provided that in no event may “C” be less than \$0.43 per share (subject to appropriate adjustment in the event of stock dividends, stock splits or similar events affecting our common stock).

As defined in the Series A Warrants, “Black Scholes Value” means the Black Scholes value of an option for one share of Common Stock at the date of the applicable Cashless Exercise, as such Black Scholes Value is determined, calculated using the Black Scholes Option Pricing Model obtained from the “OV” function on Bloomberg utilizing (i) an underlying price per share equal to 55% of the Unit price, or \$4.95 per share, (ii) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the remaining term of the Series A Warrant as of the applicable Cashless Exercise, (iii) a strike price equal to the exercise price in effect at the time of the applicable Cashless Exercise, (iv) an expected volatility equal to 135% and (v) a remaining term of such option equal to five years (regardless of the actual remaining term of the Series A Warrant). In the event that the Black Scholes Pricing Model from the “OV” function on Bloomberg is unavailable, the Company will calculate the Black Scholes Value in good faith, which calculation shall be definitive.

The Black Scholes Value (as defined above) as of March 11, 2016 was \$4.3246, and the closing bid price of Common Stock as of March 11, 2016, was \$0.18. Therefore, an exercise on that date would have resulted in the issuance of 10.06 shares of Common Stock for each Series A Warrant. Approximately 3,390,935 Series A Warrants have been exercised in cashless exercises as of March 11, 2016, resulting in the issuance of 34,053,653 shares of Common Stock. If all of the remaining 4,189,105 Series A Warrants that were issued as part of the Units sold in the Offering and part of the Units issued on August 31, 2015 were exercised pursuant to a cashless exercise and the closing bid price of our common stock as of the two trading days prior to the time of such exercise was \$0.43 per share or less and the Black Scholes Value were \$4.3246 (the Black Scholes Value as of March 11, 2016), then a total of approximately 42,130,704 shares of our common stock would be issued to the holders of such Series A Warrants. The potential for such dilutive exercise of the Series A Warrants may depress the price of our common stock regardless of the Company’s business performance, and could encourage short selling by market participants, especially if the trading price of our common stock begins to decrease.

The Series A Warrants will not be exercisable or exchangeable by the holder of such warrants to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company, determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the regulations promulgated thereunder.

In addition to (but not duplicative of) the adjustments to the exercise price and the number of shares of Common Stock issuable upon exercise of the Series A Warrants in the event of stock dividends, stock splits, reorganizations or similar events, the Series A Warrants provide for certain adjustments if the Company, at any time prior to the three year anniversary of the Issuance Date, (1) declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to all or substantially all of the holders of shares of Common Stock at any time after the Issuance Date, or (2) grants, issues or sells any options, convertible securities or rights to purchase stock, warrants, securities or other property pro rata to all or substantially all of the record holders of any class of shares of Common Stock. Further, if at any time a Series A Warrant is outstanding, the Company consummates any fundamental transaction, as described in the Series A Warrants and generally including any consolidation or merger into another corporation, or the sale of all or substantially all of our assets, or other transaction in which the Common Stock is converted into or exchanged for other securities or other consideration, the holder of any Series A Warrants will thereafter receive, the securities or other consideration to which a holder of the number of shares of Common Stock then deliverable upon the exercise or exchange of such Series A Warrants would have been entitled upon such consolidation or merger or other transaction.

The shares of common stock issuable on exercise of the Series A Warrants are duly authorized and will be, when issued, delivered and paid for in accordance with the Series A Warrants, validly issued and fully paid and non-assessable. We will authorize and reserve at least that number of shares of common stock equal to the number of shares of common stock issuable upon exercise or exchange of all outstanding Series A Warrants.

If, at any time a Series A Warrant is outstanding, we consummate any fundamental transaction, as described in the Series A Warrants and generally including any consolidation or merger into another corporation, or the sale of all or substantially all of our assets, or other transaction in which our common stock is converted into or exchanged for other securities or other consideration, the holder of any Series A Warrants will thereafter receive, the securities or other consideration to which a holder of the number of shares of common stock then deliverable upon the exercise or exchange of such Series A Warrants would have been entitled upon such consolidation or merger or other transaction.

The Series A Warrants were issued in book-entry form under a warrant agent agreement between Corporate Stock Transfer, Inc., as warrant agent, and us, and were initially represented by one or more book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

THE HOLDER OF A SERIES A WARRANT WILL NOT POSSESS ANY RIGHTS AS A STOCKHOLDER UNDER THAT SERIES A WARRANT UNTIL THE HOLDER EXERCISES THE SERIES A WARRANT.

There is no established public trading market for our Series A Warrants, and we do not expect a market to develop. We do not intend to apply to list Series A Warrants on any securities exchange. Without an active market, the liquidity of the Series A Warrants will be limited.

Series B Warrants Offered Hereby

See “Description of Series B Warrants Included in the Exchange Offer.”

Anti-Takeover Provisions

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. This provision generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date the stockholder became an interested stockholder, unless:

- prior to such date, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual meeting or special meeting of stockholders and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an “interested stockholder” as any entity or person beneficially owning 15% or more of the outstanding voting stock of a corporation, or an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of a corporation at any time within three years prior to the time of determination of interested stockholder status; and any entity or person affiliated with or controlling or controlled by such entity or person.

These statutory provisions could delay or frustrate the removal of incumbent directors or a change in control of our company. They could also discourage, impede, or prevent a merger, tender offer, or proxy contest, even if such event would be favorable to the interests of stockholders. In addition, note that while Delaware law permits companies to opt out of its business combination statute, our Certificate of Incorporation does not include this opt-out provision.

Certificate of Incorporation and Bylaws

Our current Certificate of Incorporation authorizes the issuance of “blank check” preferred stock that could be issued by our Board of Directors to defend against a takeover attempt. See “Preferred Stock” above.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Corporate Stock Transfer, Inc.

Listing

The shares of our common stock are listed on The NASDAQ Capital Market under the symbol “SKLN.” On March 16, 2016, the last reported sale price per share for our common stock as reported by The NASDAQ Capital Market was \$0.21.

CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of certain material U.S. federal income tax consequences to holders that are U.S. persons (as defined for U.S. federal income tax purposes) that own and hold Series A Warrants as capital assets, within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the "Code"), and that exchange Series A Warrants for Series B Warrants pursuant to the Exchange Offer. This discussion does not address all of the tax consequences that may be relevant to a holder based on its individual circumstances and does not address tax consequences applicable to holders that may be subject to special tax rules, including: financial institutions; insurance companies; regulated investment companies; tax-exempt organizations; dealers or traders in securities or currencies; holders that actually or constructively own 5% or more of our common stock; holders that hold Series A Warrants as part of a position in a straddle or a hedging, conversion or integrated transaction for U.S. federal income tax purposes; holders that have a functional currency other than the U.S. dollar; holders that received their Series A Warrants as compensation for the performance of services; or holders that are not U.S. persons as defined for U.S. Federal Income Tax purposes. This summary does not address any state, local or foreign tax consequences or any U.S. federal non-income tax consequences of the exchange of Series A Warrants for Series B Warrants pursuant to the Exchange Offer or any tax reporting obligations of a holder. Holders should consult their tax advisors as to the specific tax consequences to them of the Exchange Offer in light of their particular circumstances.

If an entity treated as a partnership or other pass-through entity for U.S. federal income tax purposes holds Series A Warrants, the tax treatment of a partner or owner in the partnership or other pass-through entity will generally depend on the status of the partner or owner and the activities of the partnership or other entity. Holders owning their Series A Warrants through a partnership or other pass-through entity should consult their tax advisors regarding the U.S. federal income tax consequence of the entity exchanging Series A Warrants for Series B Warrants pursuant to the Exchange Offer.

This summary is based on the Code, applicable Treasury regulations, administrative pronouncements and judicial decisions, each as in effect on the date hereof. All of the foregoing are subject to change, possibly with retroactive effect, or differing interpretations by the Internal Revenue Service ("IRS") or a court, which could affect the tax consequences described herein. You should seek advice based on your particular circumstances from an independent tax advisor.

The exchange of Series A Warrants for Series B Warrants pursuant to the Exchange Offer should be treated as a "recapitalization" within the meaning of Code Section 368(a)(1)(E) pursuant to which (i) no gain or loss should be recognized by holders on the exchange of Series A Warrants for Series B Warrants, (ii) a holder's aggregate tax basis in the Series B Warrants received in the exchange should equal the holder's aggregate tax basis in its Series A Warrants surrendered in exchange therefor allocated between the Series B Warrants in proportion to their relative fair market values, and (iii) a holder's holding period for the Series B Warrants received in the exchange should include its holding period for the surrendered Series A Warrants. Special tax basis and holding period rules apply to holders that acquired different blocks of Series A Warrants at different prices or at different times. Holders should consult their tax advisors as to the applicability of these special rules to their particular circumstances.

Certain of our "significant" holders exchanging Series A Warrants for Series B Warrants pursuant to the Exchange Offer may be required to furnish certain information to the IRS, including the fair market value of the holder's Series A Warrants exchanged for Series B Warrants pursuant to the Exchange Offer and certain tax basis information. Holders should consult their tax advisors as to the applicability of these reporting requirements to their particular circumstances.

PLAN OF DISTRIBUTION

Each broker-dealer that receives Series B Warrants for its own account pursuant to the Exchange Offer must acknowledge that it will deliver a prospectus in connection with any resale of Series B Warrants.

This prospectus, as it may be amended or supplemented from time to time, may be used by a broker-dealer in connection with resales of Series B Warrants received in exchange for Series A Warrants if the Series A Warrants were acquired as a result of market-making activities or other trading activities.

We have agreed to make this prospectus, as amended or supplemented, available to any broker-dealer to use in connection with any such resale for a period of at least 180 days after the expiration date. In addition, until (90 days after the date of this prospectus), all broker-dealers effecting transactions in the Shares may be required to deliver a prospectus.

We will not receive any proceeds from any sale of Series B Warrants by broker-dealers. Series B Warrants received by broker-dealers for their own account pursuant to the Exchange Offer may be sold from time to time in one or more transactions:

- in the over-the-counter market;
- in negotiated transactions; or
- through the writing of options on the Series B Warrants or a combination of such methods of resale.

These resales may be made:

- at market prices prevailing at the time of resale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Any such resale may be made directly to purchasers or to or through brokers or dealers. Brokers or dealers may receive compensation in the form of commissions or concessions from any such broker-dealer or the purchasers of any such Series B Warrants. An “underwriter” within the meaning of the Securities Act includes:

- any broker-dealer that resells Series B Warrants that were received by it for its own account pursuant to the Exchange Offer; or
- any broker or dealer that participates in a distribution of such Series B Warrants.

Any profit on any resale of Series B Warrants and any commissions or concessions received by any persons may be deemed to be underwriting compensation under the Securities Act. The Letter of Transmittal states that, by acknowledging that it will deliver and by delivering a prospectus, a broker-dealer will not be deemed to admit that it is an “underwriter” within the meaning of the Securities Act.

For a period of not less than 180 days after the expiration of the Exchange Offer we will promptly send additional copies of this prospectus and any amendment or supplement to this prospectus to any broker-dealer that requests those documents in the Letter of Transmittal. We have agreed to pay all expenses incident to performance of our obligations in connection with the Exchange Offer, other than commissions or concessions of any brokers or dealers. We will indemnify the holders of the Series B Warrants (including any broker-dealers) against certain liabilities, including liabilities under the Securities Act, and will contribute to payments that they may be required to make in request thereof.

LEGAL MATTERS

Maslon LLP, Minneapolis, Minnesota is representing us in connection with various legal matters associated with the Exchange Offer and has rendered an opinion regarding the legality of the issuance of the securities being registered in this prospectus. Olshan Frome Wolosky LLP, New York, New York is representing Source Capital Group, Inc., the dealer manager for the Exchange Offer.

EXPERTS

Our financial statements for the fiscal years ended December 31, 2015 and December 31, 2014 were audited by our independent auditors, Olsen Thielen & Co., Ltd., certified public accountants registered with the Public Company Accounting Oversight Board.

We have included our financial statements in this prospectus in reliance on the reports of the above-named independent auditors, given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Exchange Act. Reports filed with the SEC pursuant to the Exchange Act, including proxy statements, annual and quarterly reports, and other reports filed by the Company can be inspected and copied at the public reference facilities maintained by the SEC at the Headquarters Office, 100 F Street N.E., Room 1580, Washington, D.C. 20549. The reader may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The reader can request copies of these documents upon payment of a duplicating fee by writing to the SEC. Our filings are also available on the SEC's internet site at <http://www.sec.gov> and the Company's website at www.skylinemedical.com.

SKYLINE MEDICAL INC.

The audited financial statements for the periods ended December 31, 2015 and December 31, 2014 are included on the following pages:

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Skyline Medical Inc.

We have audited the accompanying balance sheets of Skyline Medical Inc. as of December 31, 2015 and 2014 and the related statements of operations, stockholders' equity (deficit) and cash flows for the years then ended. Skyline Medical Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Skyline Medical Inc. as of December 31, 2015 and 2014, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the company will continue as a going concern. As discussed in Note 1 to the financial statements, the company has incurred losses since inception, has an accumulated deficit and has not received significant revenue from sales of products and services. These factors raise substantial doubt about its ability to continue as a going concern. Management's plan in regard to these matters is also described in Note 1. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Olsen Thielen & Co., Ltd.

St. Paul, Minnesota
March 16, 2016

**SKYLINE MEDICAL INC.
BALANCE SHEETS**

| | December 31, 2015 | December 31, 2014 |
|--|------------------------------|------------------------------|
| ASSETS | | |
| Current Assets: | | |
| Cash | \$ 4,856,232 | \$ 16,384 |
| Accounts Receivable | 38,283 | 57,549 |
| Inventories | 231,740 | 367,367 |
| Prepaid Expense and other assets | 271,579 | 190,015 |
| Total Current Assets | 5,397,834 | 631,315 |
| Fixed Assets, net | 139,598 | 196,479 |
| Intangibles, net | 94,987 | 73,183 |
| Total Assets | \$ 5,632,419 | \$ 900,977 |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Current Liabilities: | | |
| Accounts Payable | 650,413 | 2,194,518 |
| Accrued Expenses | 864,295 | 3,066,379 |
| Short-term notes payable net of discounts of \$0 and \$194,097 (See Note 4) | - | 937,424 |
| Deferred Revenue | 5,000 | 5,000 |
| Total Current Liabilities | 1,519,708 | 6,203,321 |
| Accrued Expenses | - | 213,883 |
| Liability for equity-linked financial instruments (See Note 8) | - | - |
| Total Liabilities | \$ 1,519,708 | \$ 6,417,204 |
| Commitments and Contingencies | - | - |
| Stockholders' Equity (Deficit): | | |
| Series A Convertible Preferred Stock, \$.01 par value, \$100 Stated Value, 10,000,000 authorized, 0 and 20,550 outstanding | - | 206 |
| Series B Convertible Preferred Stock, \$.01 par value, 10,000,000 authorized, 1,895,010 and 0 outstanding | 18,950 | - |
| Common Stock, \$.01 par value, 100,000,000 authorized, 5,206,428 and 3,092,766 outstanding | 52,063 | 30,927 |
| Additional paid-in capital | 44,534,135 | 30,093,745 |
| Accumulated deficit | (40,492,437) | (35,641,105) |
| Total Stockholders' Equity (Deficit) | 4,112,711 | (5,516,227) |
| Total Liabilities and Stockholders' Equity (Deficit) | \$ 5,632,419 | \$ 900,977 |

See Notes to Financial Statements

**SKYLINE MEDICAL INC.
STATEMENTS OF OPERATIONS**

| | Year Ended December 31, | |
|---|--------------------------------|-----------------------|
| | 2015 | 2014 |
| Revenue | \$ 654,354 | \$ 951,559 |
| Cost of goods sold | 303,982 | 385,323 |
| Gross margin | 350,372 | 566,236 |
| General and administrative expense | 3,399,339 | 4,882,549 |
| Operations expense | 846,687 | 972,830 |
| Sales and marketing expense | 503,989 | 1,178,305 |
| Interest expense | 390,887 | 377,719 |
| Loss (gain) on valuation of equity-linked financial instruments | - | (11,599) |
| Total Expense | 5,140,902 | 7,399,804 |
| Net loss available to common shareholders | <u>\$ (4,790,530)</u> | <u>\$ (6,833,568)</u> |
| Loss per common share - basic and diluted | \$ (1.23) | \$ (2.29) |
| Weighted average shares used in computation - basic and diluted | 3,880,828 | 2,990,471 |

See Notes to Financial Statements

SKYLINE MEDICAL INC.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE YEARS ENDED
DECEMBER 31, 2015 and 2014

| | Preferred Stock | Common Stock | | Paid-in Capital | Deficit | Total |
|---|-----------------|--------------|-----------|-----------------|-----------------|----------------|
| | | Shares | Amount | | | |
| Balance at 12/31/13 | \$ - | 2,932,501 | \$ 29,325 | \$ 25,449,636 | \$ (28,697,415) | \$ (3,218,454) |
| Shares issued for cashless warrant exercise at \$15.00 per share | | 1,728 | 17 | 1,279 | | 1,296 |
| Shares issued for option exercise at \$1.25 per share | | 4,336 | 43 | 5,387 | | 5,430 |
| Shares issued at \$20.63 per share as Investor Relations compensation | | 2,000 | 20 | 41,230 | | 41,250 |
| Shares issued for cashless warrant exercise at \$12.75 per share | | 3,323 | 33 | 2,460 | | 2,493 |
| Shares issued for an option exercise at \$5.25 per share | | 267 | 3 | 1,397 | | 1,400 |
| Shares issued for cashless warrant exercise at \$.75 per share | | 2,174 | 22 | 1,608 | | 1,630 |
| Shares issued for warrant exercise at \$13.50 per share | | 2,667 | 27 | 35,973 | | 36,000 |
| Shares issued at \$18.75 per share as Investor Relations compensation | | 1,333 | 13 | 24,987 | | 25,000 |
| Reduction in escrow account per settlement agreement | | (4,444) | (44) | (3,289) | | (3,333) |
| Shares issued for cashless warrant exercise at \$7.50 per share | | 4,807 | 48 | 3,557 | | 3,605 |
| Shares issued for cashless warrant exercise at \$5.63 per share | | 3,112 | 31 | 2,302 | | 2,333 |
| Shares issued for cashless warrant exercise at \$12.75 per share | | 299 | 3 | 221 | | 224 |
| Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$19.50 per share | | 972 | 10 | 18,909 | (18,919) | - |
| Vesting Expense | | | - | 705,434 | | 705,434 |
| Options issued as part of employee bonus | | | - | 694,500 | | 694,500 |
| Shares issued for combined cashless and cash warrant exercise @ \$11.25 per share. | | 7,778 | 78 | 52,422 | | 52,500 |
| Issuance of Preferred stock | 206 | | - | 2,054,795 | | 2,055,001 |
| Shares issued to Investor Relations consultant exercisable at \$11.25 per share | | 2,133 | 21 | 23,979 | | 24,000 |
| Shares issued to Investor Relations consultant exercisable at \$18.75 per share | | 1,333 | 13 | 24,987 | | 25,000 |
| Shares issued for cashless warrant exercise at \$13.50 per share | | 3,725 | 37 | 2,757 | | 2,794 |
| Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$19.50 per share | | 1,561 | 16 | 30,384 | (30,400) | - |
| Value of equity instruments issued with debt | | | - | 313,175 | | 313,175 |
| Shares issued for cashless warrant exercise at \$9.75 per share | | 1,410 | 14 | 1,044 | | 1,058 |
| Shares issued for a cash warrant exercise at \$5.63 per share | | 11,111 | 111 | 62,389 | | 62,500 |
| Shares issued for an option exercise at \$5.25 per share | | 333 | 3 | 1,747 | | 1,750 |
| Shares issued for a note conversion at \$6.68 per share | | 3,018 | 30 | 19,970 | | 20,000 |
| Shares issued for a note conversion at \$6.68 per share | | 3,019 | 30 | 19,970 | | 20,000 |
| Shares issued for a note conversion at \$5.85 per share | | 3,435 | 34 | 19,966 | | 20,000 |
| Shares issued for a note conversion at \$5.03 per share | | 3,894 | 38 | 19,962 | | 20,000 |
| Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$19.50 per share | | 1,561 | 16 | 30,385 | (30,401) | - |
| Shares issued for a note conversion at \$5.14 per share | | 3,894 | 39 | 19,961 | | 20,000 |
| Shares issued for a note conversion at \$5.00 per share | | 3,997 | 40 | 19,960 | | 20,000 |

| | | | | |
|---|-----------|-----------|-----------|---------------|
| Shares issued for a note conversion at \$5.26 per share | 3,804 | 38 | 19,962 | 20,000 |
| Shares issued for a note conversion at \$5.26 per share | 5,706 | 57 | 29,943 | 30,000 |
| Shares issued for a note conversion at \$5.95 per share | 5,044 | 50 | 29,950 | 30,000 |
| Shares issued into an escrow account per settlement agreement | 13,700 | 137 | | 137 |
| Shares issued for a note conversion at \$5.05 per share | 55,568 | 556 | 280,060 | 280,616 |
| Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$19.50 per share | 1,561 | 16 | 30,385 | (30,402) |
| Shares adjusted for rounding per reverse stock split | 106 | 1 | 1 | 2 |
| Net loss | | - | - | (6,833,568) |
| Balance at 12/31/2014 | \$ 206 | 3,092,766 | \$ 30,927 | \$ 30,093,745 |
| Shares issued to 16 shareholders of Series A Convertible Preferred Stock Adjustment as converted to common shares at \$9.75 per share | 3,122 | 31 | (31) | - |
| Reduction in escrow account per settlement agreement | (8,889) | (89) | (6,578) | (6,667) |
| Shares issued for a note conversion at \$2.90 per share | 3,447 | 34 | 9,966 | 10,000 |
| Shares issued for a note conversion at \$2.96 per share | 6,762 | 68 | 19,932 | 20,000 |
| Shares issued for a note conversion at \$2.91 per share | 10,313 | 103 | 29,897 | 30,000 |
| Shares issued for a note conversion at \$2.77 per share | 12,098 | 120 | 33,358 | 33,478 |
| Shares issued for a note conversion at \$2.25 per share | 15,552 | 156 | 34,844 | 35,000 |
| Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$9.75 per share | 3,121 | 31 | 30,369 | (30,401) |
| Shares issued for a note conversion at \$2.00 per share | 20,000 | 200 | 39,800 | 40,000 |
| Shares issued for a note conversion at \$2.27283 per share | 87,997 | 880 | 199,120 | 200,000 |
| Shares issued for a note conversion at \$2.0179 per share | 14,867 | 149 | 29,851 | 30,000 |
| Shares issued for a note conversion at \$2.00 per share | 15,000 | 150 | 29,850 | 30,000 |
| Shares issued for a note conversion at \$1.92417 per share | 12,993 | 130 | 24,870 | 25,000 |
| Shares issued for a note conversion at \$1.8578 per share | 16,148 | 162 | 29,838 | 30,000 |
| Shares issued to 16 shareholders of Series A Convertible Preferred Stock Dividends as converted to common shares at \$9.75 per share | 3,121 | 31 | 30,371 | (30,401) |
| Vesting Expense | | - | 871,877 | 871,877 |
| Shares issued in public offering; net | 16,667 | 1,666,667 | 16,667 | 13,027,546 |
| Preferred stock conversion | 2,077 | 228,343 | 2,283 | (4,360) |
| Series A warrant exercise | 3,000 | 30 | 9,870 | 9,900 |
| Net loss | | - | - | (4,790,530) |
| Balance @ 12/31/2015 | \$ 18,950 | 5,206,428 | \$ 52,063 | \$ 44,534,135 |

See Notes to Financial Statements

**SKYLINE MEDICAL INC.
STATEMENTS OF CASH FLOWS**

| | Year Ended December 31, | |
|---|----------------------------|----------------|
| | 2015 | 2014 |
| Cash flow from operating activities: | | |
| Net loss | (4,790,530) | (6,833,568) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 78,566 | 63,040 |
| Vested stock options and warrants | 871,877 | 723,367 |
| Equity instruments issued for management and consulting | (6,667) | 112,054 |
| Amortization of debt discount | 219,097 | 247,338 |
| Penalty on debt provision | 10,031 | - |
| Loss on Sales of Equipment | 17,076 | - |
| (Gain) loss on valuation of equity-linked instruments | - | (11,599) |
| Changes in assets and liabilities: | | |
| Accounts receivable | 19,266 | 39,696 |
| Inventories | 135,627 | (245,192) |
| Prepaid expense and other assets | (81,564) | (129,427) |
| Accounts payable | (1,544,105) | 1,132,410 |
| Accrued expenses | (2,415,967) | 1,594,468 |
| Deferred Revenue | - | (64,000) |
| Net cash used in operating activities: | (7,487,293) | (3,371,413) |
| Cash flow from investing activities: | | |
| Purchase of fixed assets | (32,470) | (101,409) |
| Purchase of intangibles | (28,095) | (19,828) |
| Net cash used in investing activities | (60,565) | (121,237) |
| Cash flow from financing activities: | | |
| Proceeds from long-term and convertible debt | 250,000 | 1,500,000 |
| Principal payments on debt | (933,074) | (305,000) |
| Net proceeds from issuance of preferred stock | 18,950 | 2,055,000 |
| Net proceeds from issuance of common stock | 13,051,830 | 157,081 |
| Net cash provided by financing activities | 12,387,706 | 3,407,081 |
| Net increase (decrease) in cash | 4,839,848 | (85,569) |
| Cash at beginning of period | 16,384 | 101,953 |
| Cash at end of period | <u>4,856,232</u> | <u>16,384</u> |
| Non cash transactions: | | |
| Common stock issued for accrued interest/bonus | - | 694,500 |
| Common stock issued to satisfy debt | <u>483,478</u> | <u>480,616</u> |

See Notes to Financial Statements

SKYLINE MEDICAL INC.
NOTES TO FINANCIAL STATEMENTS

NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations and Continuance of Operations

Skyline Medical Inc. (the "Company") was incorporated under the laws of the State of Minnesota in 2002. Effective August 6, 2013, the Company changed its name to Skyline Medical Inc. As of December 31, 2015, the registrant had 5,206,428 shares of common stock, par value \$.01 per share, outstanding, adjusted for a 1-for-75 reverse stock split effective October 24, 2014. In this Report, all numbers of shares and per share amounts, as appropriate, have been stated to reflect the reverse stock split. Pursuant to an Agreement and Plan of Merger dated effective December 16, 2013, the Company merged with and into a Delaware corporation with the same name that was its wholly-owned subsidiary, with such Delaware Corporation as the surviving corporation of the merger. The Company has developed an environmentally safe system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. The Company also makes ongoing sales of our proprietary cleaning fluid and filters to users of our systems. In April 2009, the Company received 510(k) clearance from the FDA to authorize the Company to market and sell its STREAMWAY FMS products.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company has suffered recurring losses from operations and had a stockholders' deficit until August 31, 2015 whereupon the Company closed its public offering of units of common stock, Series B Convertible Preferred Stock and Series A Warrants (the "Units"). There remains though, substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Since inception to December 31, 2015, the Company raised approximately \$22,732,961 in equity, inclusive of \$2,055,000 from a private placement of Series A Convertible Preferred Stock, \$13,555,003 from the public offering of Units and \$5,685,000 in debt financing. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

Recent Accounting Developments

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, *Revenue from Contracts with Customers* and created a new topic in the FASB Accounting Standards Codification ("ASC"), Topic 606. The new standard provides a single comprehensive revenue recognition framework for all entities and supersedes nearly all existing U.S. GAAP revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity should recognize revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is designed to create greater comparability for financial statement users across industries and also requires enhanced disclosures. The amendments are effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early application is not permitted. We are currently evaluating the impact this guidance may have on our financial statements and related disclosures.

In June 2014, the FASB issued ASU 2014-12, *Compensation - Stock Compensation* providing explicit guidance on how to account for share-based payments granted to employees in which the terms of the award provide that a performance target that affects vesting could be achieved after the requisite service period. The amendments in this Update are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. We are currently evaluating the impact this guidance may have on our financial statements.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The new standard requires management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The standard is effective for public entities for annual and interim periods beginning after December 15, 2016, with early adoption permitted. We are currently evaluating the impact this guidance may have on our financial statements.

In April 2015, the FASB issued ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. Debt issuance costs related to a recognized debt liability will be presented on the balance sheet as a direct deduction from the debt liability, similar to the presentation of debt discounts, rather than as an asset. Amortization of these costs will continue to be reported as interest expense. ASU 2015-03 is effective for annual and interim reporting periods beginning after December 15, 2015. Early adoption is permitted. The adoption of this ASU is not expected to have an impact on our financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*, requiring that inventory be measured at the lower of cost and net realizable value. Net realizable value is defined as estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This ASU is effective within annual periods beginning on or after December 15, 2016, including interim periods within that reporting period. We are currently evaluating the impact this guidance may have on our financial statements.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740)* providing guidance on the balance sheet classification of deferred taxes. The guidance requires that deferred tax assets and liabilities to be classified as noncurrent in the Balance Sheet. The guidance is effective for fiscal years beginning after December 15, 2016 and for interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact this guidance may have on our financial statements.

We reviewed all other significant newly issued accounting pronouncements and determined they are either not applicable to our business or that no material effect is expected on our financial position and results of our operations.

Valuation of Intangible Assets

We review identifiable intangible assets for impairment in accordance with ASC 350 — Intangibles — Goodwill and Other, whenever events or changes in circumstances indicate the carrying amount may not be recoverable. Our intangible assets are currently solely the costs of obtaining trademarks and patents. Events or changes in circumstances that indicate the carrying amount may not be recoverable include, but are not limited to, a significant change in the medical device marketplace and a significant adverse change in the business climate in which we operate. If such events or changes in circumstances are present, the undiscounted cash flows method is used to determine whether the intangible asset is impaired. Cash flows would include the estimated terminal value of the asset and exclude any interest charges. If the carrying value of the asset exceeds the undiscounted cash flows over the estimated remaining life of the asset, the asset is considered impaired, and the impairment is measured by reducing the carrying value of the asset to its fair value using the discounted cash flows method. The discount rate utilized is based on management's best estimate of the related risks and return at the time the impairment assessment is made.

Accounting Policies and Estimates

The presentation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Presentation of Taxes Collected from Customers

Sales taxes are imposed on the Company's sales to nonexempt customers. The Company collects the taxes from customers and remits the entire amounts to the governmental authorities. The Company's accounting policy is to exclude the taxes collected and remitted from revenues and expenses.

Shipping and Handling

Shipping and handling charges billed to customers are recorded as revenue. Shipping and handling costs are recorded within cost of goods sold on the statement of operations.

Advertising

Advertising costs are expensed as incurred. Advertising expenses were \$8,220 in 2015, and \$19,394 in 2014.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs were approximately \$261,000 and \$394,000 for 2015 and 2014, respectively.

Revenue Recognition

The Company recognizes revenue in accordance with the SEC's Staff Accounting Bulletin Topic 13 Revenue Recognition and ASC 605- Revenue Recognition.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectability is probable. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination based on the shipping terms of the transaction. The Company's standard terms specify that shipment is FOB Skyline and the Company will, therefore, recognize revenue upon shipment in most cases. This revenue recognition policy applies to shipments of the STREAMWAY FMS units as well as shipments of cleaning solution kits. When these conditions are satisfied, the Company recognizes gross product revenue, which is the price it charges generally to its customers for a particular product. Under the Company's standard terms and conditions, there is no provision for installation or acceptance of the product to take place prior to the obligation of the customer. The customer's right of return is limited only to the Company's standard one-year warranty whereby the Company replaces or repairs, at its option, and it would be rare that the STREAMWAY FMS unit or significant quantities of cleaning solution kits may be returned. Additionally, since the Company buys both the STREAMWAY FMS units and cleaning solution kits from "turnkey" suppliers, the Company would have the right to replacements from the suppliers if this situation should occur.

Receivables

Receivables are reported at the amount the Company expects to collect on balances outstanding. The Company provides for probable uncollectible amounts through charges to earnings and credits to the valuation based on management's assessment of the current status of individual accounts, changes to the valuation allowance have not been material to the financial statements.

Inventories

Inventories are stated at the lower of cost or market, with cost determined on a first-in, first-out basis. Inventory balances are as follows:

| | December 31, 2015 | December 31, 2014 |
|-----------------|----------------------|----------------------|
| Finished goods | \$ 30,237 | \$ 88,362 |
| Raw materials | 162,623 | 237,556 |
| Work-In-Process | 38,880 | 41,449 |
| Total | <u>\$ 231,740</u> | <u>\$ 367,367</u> |

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets. Estimated useful asset life by classification is as follows:

| | Years | | |
|--------------------------------|-------|---|---|
| Computers and office equipment | 3 | - | 7 |
| Leasehold improvements | | 5 | |
| Manufacturing Tooling | 3 | - | 7 |
| Demo Equipment | | 3 | |

The Company's investment in Fixed Assets consists of the following:

| | December 31, 2015 | December 31, 2014 |
|--------------------------------|----------------------|----------------------|
| Computers and office equipment | \$ 153,553 | \$ 123,708 |
| Leasehold Improvements | 23,874 | 23,874 |
| Manufacturing Tooling | 97,288 | 97,288 |
| Demo Equipment | 8,962 | 30,576 |
| Total | <u>283,677</u> | <u>275,446</u> |
| Less: Accumulated Depreciation | 144,079 | 78,967 |
| Total Fixed Assets, Net | <u>\$ 139,598</u> | <u>\$ 196,479</u> |

Upon retirement or sale, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

Intangible Assets

Intangible assets consist of trademarks and patent costs. These assets are not subject to amortization until the property patented is in production. The assets are reviewed for impairment annually, and impairment losses, if any, are charged to operations when identified.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740- *Income Taxes* ("ASC 740"). Under ASC 740, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company reviews income tax positions expected to be taken in income tax returns to determine if there are any income tax uncertainties. The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not that the tax positions will be sustained on examination by taxing authorities, based on technical merits of the positions. The Company has identified no income tax uncertainties.

Tax years subsequent to 2012 remain open to examination by federal and state tax authorities.

Patents and Intellectual Property

On January 25th, 2014 the Company filed a non-provisional PCT Application No. PCT/US2014/013081 claiming priority from the U.S. Provisional Patent Application, number 61756763 which was filed one year earlier on January 25th, 2013. The Patent Cooperation Treaty (“PCT”) allows an applicant to file a single patent application to seek patent protection for an invention simultaneously in each of the 148 countries of the PCT, including the United States. By filing this single “international” patent application through the PCT, it is easier and more cost effective than filing separate applications directly with each national or regional patent office in which patent protection is desired.

Our PCT patent application is for the new model of the surgical fluid waste management system. We obtained a favorable International Search Report from the PCT searching authority indicating that the claims in our PCT application are patentable (i.e., novel and non-obvious) over the cited prior art. A feature claimed in the PCT application is the ability to maintain continuous suction to the surgical field while measuring, recording and evacuating fluid to the facilities sewer drainage system. This provides for continuous operation of the STREAMWAY System unit in suctioning waste fluids, which means that suction is not interrupted during a surgical operation, for example, to empty a fluid collection container or otherwise dispose of the collected fluid.

The Company holds the following granted patents in the United States and a pending application in the United States on its earlier models: US7469727, US8123731 and U.S. Publication No. US20090216205 (collectively, the “Patents”). These Patents will begin to expire on August 8, 2023.

In July 2015, Skyline Medical filed an international (PCT) patent application for its fluid waste collection system and received a favorable determination by the International Searching Authority finding that all of the claims satisfy the requirements for novelty, inventive step and industrial applicability. Skyline anticipates that the favorable International Search Report will result in allowance of its various national applications.

Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash. The Company places its cash with high credit quality financial institutions and, by policy, generally limits the amount of credit exposure to any one financial institution. The Company had a credit risk concentration as a result of depositing \$4,621,764 of funds in excess of insurance limits in a single bank.

Product Warranty Costs

In 2015, the Company incurred approximately \$56,201 in current warranty costs.

Segments

The Company operates in one segment for the sale of its medical device and consumable products. Substantially all of the Company’s assets, revenues, and expenses for 2015 and 2014 were located at or derived from operations in the United States. There were no revenues from sales outside of the United States.

Risks and Uncertainties

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with regulations of the FDA and other governmental agencies.

NOTE 2 – DEVELOPMENT STAGE OPERATIONS

The Company was formed April 23, 2002. Since inception through December 31, 2015, 5,206,428 shares of common stock have been issued between par value and \$125.25. Operations since incorporation have primarily been devoted to raising capital, obtaining financing, development of the Company’s product, administrative services, customer acceptance and sales and marketing strategies.

NOTE 3 – STOCKHOLDERS' EQUITY (DEFICIT), STOCK OPTIONS AND WARRANTS

Public Offering of Units

On August 31, 2015 (the "Issuance Date"), the Company completed a public offering (the "Offering") of 1,666,667 Units (the "Units") as described below. The public offering price in the Offering was \$9.00 per Unit, and the purchase price for the underwriter of the Offering (the "Underwriter") was \$8.28 per Unit, resulting in an underwriting discount and commission of \$0.72 (or 8.00%) per Unit and total net proceeds to the Company before expenses of \$13.8 million. The Company had granted the Underwriter an option for a period of 45 days to purchase up to an additional 250,000 Units solely to cover over-allotments. The Underwriter chose not to purchase any additional Units under the over-allotment option. The Company paid to the Underwriter a non-accountable expense allowance equal to 1% of the gross proceeds of the Offering and agreed to reimburse expenses incurred by the Underwriter up to \$70,000.

On August 31, 2015, as a result of the communication of the Offering and the issuance of the 228,343 Exchange Units in the Unit Exchange described below, the Company issued a total of 1,895,010 Units, comprised of a total of aggregate of 1,895,010 shares of Common Stock, 1,895,010 shares of Series B Preferred Stock and 7,580,040 Series A Warrants.

Each Unit consisted of one share of common stock, par value \$0.01 per share (the "Common Stock"), one share of Series B Convertible Preferred Stock ("Series B Preferred Stock") and four Series A Warrants. The shares of Common Stock, the shares of Series B Preferred Stock and the Series A Warrants that comprise the Units automatically separated on February 29, 2016.

For a description of the terms of the Series B Convertible Preferred Stock included within the Units, see "Certificate of Designation for Series B Preferred Stock" below. For a description of the terms of the Series A Warrants included within the Units, see "Series A Warrants" below.

Series A Warrants. The Series A Warrants separated from the Series B Convertible Preferred Stock and the Common Stock included within the Units as described above and are currently exercisable. The Series A Warrants will terminate on August 31, 2020. Each Series A Warrant is exercisable into one share of Common Stock at an initial cash exercise price of \$4.95 per share. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Common Stock and the exercise price.

Holders may exercise Series A Warrants by paying the exercise price in cash or, in lieu of payment of the exercise price in cash, by electing to receive a number of shares of Common Stock equal to the Black Scholes Value (as defined below) based upon the number of shares the holder elects to exercise. The number of shares of Common Stock to be delivered will be determined according to the following formula, referred to as the "Cashless Exercise."

$$\text{Total Shares} = (A \times B) / C$$

Where:

- Total Shares is the number of shares of Common Stock to be issued upon a Cashless Exercise.
- A is the total number of shares with respect to which the Series A Warrant is then being exercised.
- B is the Black Scholes Value (as defined below).
- C is the closing bid price of the Common Stock as of two trading days prior to the time of such exercise, provided that in no event may "C" be less than \$0.43 per share (subject to appropriate adjustment in the event of stock dividends, stock splits or similar events affecting the Common Stock).

The Black Scholes Value (as defined above) as of March 11, 2016 was \$4.3246, and the closing bid price of Common Stock as of March 11, 2016, was \$0.18. Therefore, an exercise on that date would have resulted in the issuance of 10.06 shares of Common Stock for each Series A Warrant. Approximately 3,390,935 Series A Warrants have been exercised in cashless exercises as of March 11, 2016, resulting in the issuance of 34,053,653 shares of Common Stock. If all of the remaining 4,189,105 Series A Warrants that were issued as part of the Units sold in the Offering and part of the Units issued on August 31, 2015 were exercised pursuant to a cashless exercise and the closing bid price of our common stock as of the two trading days prior to the time of such exercise was \$0.43 per share or less and the Black Scholes Value were \$4.3246 (the Black Scholes Value as of March 11, 2016), then a total of approximately 42,130,704 shares of our common stock would be issued to the holders of such Series A Warrants. The potential for such dilutive exercise of the Series A Warrants may depress the price of our common stock regardless of the Company's business performance, and could encourage short selling by market participants, especially if the trading price of our common stock begins to decrease.

The Series A Warrants will not be exercisable or exchangeable by the holder of such warrants to the extent (and only to the extent) that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company, determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the regulations promulgated thereunder.

In addition to (but not duplicative of) the adjustments to the exercise price and the number of shares of Common Stock issuable upon exercise of the Series A Warrants in the event of stock dividends, stock splits, reorganizations or similar events, the Series A Warrants provide for certain adjustments if the Company, at any time prior to the three year anniversary of the Issuance Date, (1) declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to all or substantially all of the holders of shares of Common Stock at any time after the Issuance Date, or (2) grants, issues or sells any options, convertible securities or rights to purchase stock, warrants, securities or other property pro rata to all or substantially all of the record holders of any class of shares of Common Stock. Further, if at any time a Series A Warrant is outstanding, the Company consummates any fundamental transaction, as described in the Series A Warrants and generally including any consolidation or merger into another corporation, or the sale of all or substantially all of our assets, or other transaction in which the Common Stock is converted into or exchanged for other securities or other consideration, the holder of any Series A Warrants will thereafter receive, the securities or other consideration to which a holder or the number of shares of Common Stock then deliverable upon the exercise or exchange of such Series A Warrants would have been entitled upon such consolidation or merger or other transaction.

Unit Purchase Option. The Company, in connection with the Offering, entered into a Unit Purchase Option Agreement, dated as of August 31, 2015 (the "Unit Purchase Option"), pursuant to which the Company granted the Underwriter the right to purchase from the Company up to a number of Units equal to 5% of the Units sold in the Offering (or up to 83,333 Units) at an exercise price equal to 125% of the public offering price of the Units in the Offering, or \$11.25 per Unit. The Unit Purchase Option expires on August 25, 2018.

Series B Preferred Stock. Each share of Series B Preferred Stock is convertible into one share of Common Stock (subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events) on the six month anniversary of the Issuance Date or on the date of an Early Separation. In addition, the Series B Preferred Stock will automatically convert into shares of common stock upon the occurrence of a fundamental transaction, as described in the certificate of designations for the Series B Preferred Stock but including mergers, sales of the company's assets, changes in control and similar transactions. The Series B Preferred Stock is not convertible by the holder of such preferred stock to the extent (and only to the extent that the holder or any of its affiliates would beneficially own in excess of 4.99% of the common stock of the Company. The Series B Preferred Stock has no voting rights, except for the right to approve certain amendments to the certificate of designations or similar actions. With respect to payment of dividends and distribution of assets upon liquidation or dissolution or winding up of the Company, the Series B Preferred Stock shall rank equal to the common stock of the Company. No sinking fund has been established for the retirement or redemption of the Series B Preferred Stock.

Unit Exchange. On February 4, 2014, the Company raised \$2,055,000 in gross proceeds from a private placement of 20,550 shares of Series A Convertible Preferred Stock, par value \$0.01, with a stated value of \$100 per share (the "Series A Preferred Shares") and warrants to purchase shares of the Company's common stock. The Series A Preferred Shares and warrants were sold to investors pursuant to a Securities Purchase Agreement, dated as of February 4, 2014. On August 31, 2015, the Company issued a total of 228,343 Units (the "Exchange Units") in exchange for the outstanding Series A Preferred Stock which were then cancelled pursuant to an agreement with the holders of the Series A Preferred Shares. The warrants that were issued in connection with the issuance of the Series A Preferred Shares remained outstanding; however, the warrant amounts were reduced so that the warrants are exercisable into an aggregate of 84,770 shares of the Company's common stock. The Exchange Units were exempt from registration under Section 3(a)(9) of the Securities Act. On August 31, 2015, the Company filed a termination certificate with the Delaware Secretary of State. Following that date there were no shares of Series A Preferred Stock outstanding, and the previously authorized shares of Series A Preferred Stock resumed the status of authorized but unissued and undesignated shares of preferred stock of the Company.

Redemption of Convertible Notes. In connection with the closing of the Offering, \$933,074 aggregate principal amount of Convertible Notes plus interest and a 40% redeemable premium were redeemed for total payments of \$1,548,792. See Note 4. Of this amount, approximately \$167,031 was paid to its affiliates in redemption of their Convertible Notes.

Equity Incentive Plan

The Company has an equity incentive plan, which allows issuance of incentive and non-qualified stock options to employees, directors and consultants of the Company, where permitted under the plan. The exercise price for each stock option is determined by the Board of Directors. Vesting requirements are determined by the Board of Directors when granted and currently range from immediate to three years. Options under this plan have terms ranging from three to ten years.

Accounting for share-based payment

The Company has adopted ASC 718 - *Compensation-Stock Compensation* ("ASC 718"). Under ASC 718 stock-based employee compensation cost is recognized using the fair value based method for all new awards granted after January 1, 2006 and unvested awards outstanding at January 1, 2006. Compensation costs for unvested stock options and non-vested awards that were outstanding at January 1, 2006, are being recognized over the requisite service period based on the grant-date fair value of those options and awards, using a straight-line method. We elected the modified-prospective method under which prior periods are not retroactively restated.

ASC 718 requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model or other acceptable means. The Company uses the Black-Scholes option valuation model which requires the input of significant assumptions including an estimate of the average period of time employees will retain vested stock options before exercising them, the estimated volatility of the Company's common stock price over the expected term, the number of options that will ultimately be forfeited before completing vesting requirements, the expected dividend rate and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. The assumptions the Company uses in calculating the fair value of stock-based payment awards represent the Company's best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and the Company uses different assumptions, the Company's equity-based compensation expense could be materially different in the future.

Since the Company's common stock has no significant public trading history, and the Company has experienced no significant option exercises in its history, the Company is required to take an alternative approach to estimating future volatility and estimated life and the future results could vary significantly from the Company's estimates. The Company compiled historical volatilities over a period of 2 to 7 years of 15 small-cap medical companies traded on major exchanges and 10 mid-range medical companies on the OTC Bulletin Board and combined the results using a weighted average approach. In the case of ordinary options to employees the Company determined the expected life to be the midpoint between the vesting term and the legal term. In the case of options or warrants granted to non-employees, the Company estimated the life to be the legal term unless there was a compelling reason to make it shorter.

When an option or warrant is granted in place of cash compensation for services, the Company deems the value of the service rendered to be the value of the option or warrant. In most cases, however, an option or warrant is granted in addition to other forms of compensation and its separate value is difficult to determine without utilizing an option pricing model. For that reason the Company also uses the Black-Scholes option-pricing model to value options and warrants granted to non-employees, which requires the input of significant assumptions including an estimate of the average period the investors or consultants will retain vested stock options and warrants before exercising them, the estimated volatility of the Company's common stock price over the expected term, the number of options and warrants that will ultimately be forfeited before completing vesting requirements, the expected dividend rate and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based consulting and/or compensation and, consequently, the related expense recognized.

Since the Company has limited trading history in its stock and no first-hand experience with how its investors and consultants have acted in similar circumstances, the assumptions the Company uses in calculating the fair value of stock-based payment awards represent its best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and the Company uses different assumptions, the Company's equity-based consulting and interest expense could be materially different in the future.

Valuation and accounting for options and warrants

The Company determines the grant date fair value of options and warrants using a Black-Scholes option valuation model based upon assumptions regarding risk-free interest rate, expected dividend rate, volatility and estimated term.

In January 2014 the Company issued 4,336 shares of common stock to the former CEO at \$1.25 per share upon his exercising options.

In January through March 2014, 9 warrant holders exercised warrants through a cashless exercise for a total of 15,442 shares of common stock.

In January and February 2014 the Company issued warrants to purchase 21,538 shares pursuant to a February 4, 2014 private placement whereby the Company issued 20,550 shares of Series A Convertible Preferred Stock raising gross proceeds of \$2,055,000. The warrants are at an exercise price of \$24.38.

In February 2014 the Company issued a warrant to purchase 1,482 shares of common stock at an exercise price of \$20.25 to a major shareholder Dr. Samuel Herschkowitz. The warrant is in consideration for a bridge loan extended in December 2013 that has been paid in February 2014.

On March 31, 2014, the Company issued dividends to the Purchasers of the Preferred Shares as described above. The dividends are at an annual rate of 6% of the stated value of the Preferred Shares paid on a quarterly basis in the form of common stock per a stipulated \$19.50 per share. As a result 970 shares of common stock were issued to 16 holders of Preferred Shares.

In March 2014, the Company issued 4,444 shares of common stock to a warrant holder for a partial cash exercise at \$11.25 per share; issued 3,333 shares to the holder via the cashless exercise of the remainder of the warrant.

In June 2014, the Company issued 3,725 shares of common stock to a warrant holder exercising cashless warrants.

On June 30, 2014, the Company issued dividends to the Purchasers of the Preferred Shares as described above. The dividends are at an annual rate of 6% of the stated value of the Preferred Shares paid on a quarterly basis in the form of common stock per a stipulated \$19.50 per share. As a result 1,561 shares of common stock were issued to 16 holders of Preferred Shares.

On June 30, 2014, the Company issued a warrant to purchase 5,431 shares of common stock at an exercise price of \$12.38 to SOK Partners, LLC, in consideration for a bridge loan in the form of convertible notes. On September 9, 2014 the Resale Registration Statement went into effect. The convertible note agreement provided an immediate approximately 11% reduction to the warrant agreement. Therefore, the warrant has been adjusted to purchase 4,831 shares of common stock at an exercise price of \$12.38 to SOK Partners, LLC in consideration for a bridge loan.

In July 2014, the Company issued warrants to purchase 28,986 shares of common stock at an exercise price of \$12.38 to two lenders in consideration for a bridge loan in the form of convertible notes. The shares above reflect approximately an 11% reduction resulting from the Resale Registration Statement that went effective September 9, 2014.

In August 2014, the Company issued warrants to purchase 61,539 of common stock at an exercise price of \$24.38 to the Purchasers of the Preferred Shares. The Securities Purchase Agreement with the Preferred Shareholders stipulated that if the Company was not listed on either the NASDAQ Stock Market, the New York Stock Exchange or the NYSE MKT within 180 days of closing the agreement then warrants to purchase the above additional shares would be issued in aggregate to the Preferred Shareholders.

In August and September 2014, the Company issued warrants to purchase 37,440 shares of common stock at an exercise price of \$12.38 to four lenders in consideration for a bridge loan in the form of convertible notes. The shares above reflect the approximate 11% reduction resulting from the Resale Registration Statement that went effective September 9, 2014.

On September 30, 2014, the Company issued dividends to the Purchasers of the Preferred Shares as described above. The dividends are at an annual rate of 6% of the stated value of the Preferred Shares paid on a quarterly basis in the form of common stock per a stipulated \$19.50 per share. As a result 1,561 shares of common stock were issued to 16 holders of Preferred Shares.

In November 2014, the Company issued 13,700 shares of common stock, par value \$0.01, in escrow for debt settlement.

On December 31, 2014, the Company issued dividends to the Purchasers of the Preferred Shares as described above. The dividends are at an annual rate of 6% of the stated value of the Preferred Shares paid on a quarterly basis in the form of common stock per a stipulated \$19.50 per share. As a result 1,559 shares of common stock were issued to 16 holders of Preferred Shares.

For grants of stock options and warrants in 2014 the Company used a 1.44% to 2.75% risk-free interest rate, 0% dividend rate, 59% or 66% volatility and estimated terms of 5 or 10 years. Value computed using these assumptions ranged from \$3.2006 to \$13.9195 per share.

In January 2015, the Company issued a dividend adjustment to the Purchasers of the Preferred Shares as described above. Certain previous dividends paid were calculated with an exercise price of \$19.50 per share, but should have been calculated at \$9.75 per share. As a result 3,122 shares of common stock were issued to 16 holders of Preferred Shares.

On March 31, 2015, the Company issued dividends to the Purchasers of the Preferred Shares as described above. The dividends are at an annual rate of 6% of the stated value of the Preferred Shares paid on a quarterly basis in the form of common stock per a stipulated \$9.75 per share. As a result 3,121 shares of common stock were issued to 16 holders of Preferred Shares.

On June 30, 2015, the Company issued dividends to Purchases of the Preferred Shares as described above. The dividends are at an annual rate of 6% of the stated value of the Preferred Shares paid on a quarterly basis in the form of common stock per a stipulated \$9.75 per share. As a result 3,121 shares of common stock were issued to 16 holders of Preferred Shares.

For grants of stock options and warrants in 2015 the Company used a 1.63% to 2.35% risk-free interest rate, 0% dividend rate, 59% to 66% volatility and estimated terms of 5 to 10 years. Value computed using these assumptions ranged from \$0.2750 to \$5.5695 per share.

The following summarizes transactions for stock options and warrants for the periods indicated:

| | Stock Options | | Warrants | |
|----------------------------------|------------------|------------------------|------------------|------------------------|
| | Number of Shares | Average Exercise Price | Number of Shares | Average Exercise Price |
| Outstanding at December 31, 2013 | 385,733 | \$ 6.75 | 461,920 | \$ 10.50 |
| Issued | 75,683 | 8.12 | 161,375 | 3.81 |
| Expired | (7,879) | 23.58 | (81,851) | 13.54 |
| Exercised | (4,936) | 1.76 | (40,722) | 8.38 |
| Outstanding at December 31, 2014 | 448,601 | \$ 7.51 | 500,722 | \$ 7.95 |
| Issued | 354,253 | 2.76 | 7,581,722 | 4.95 |
| Cancelled | (19,136) | 11.73 | (1,967) | 11.34 |
| Exercised | - | - | (3,000) | 4.95 |
| Outstanding at December 31, 2015 | 783,718 | \$ 5.33 | 8,077,477 | \$ 5.14 |

At December 31, 2015, 780,718 stock options are fully vested and currently exercisable with a weighted average exercise price of \$5.29 and a weighted average remaining term of 8.17 years. There are 8,077,477 warrants that are fully vested and exercisable. Stock-based compensation recognized in 2015 and 2014 was \$871,877 and \$723,367, respectively. The Company has \$32,682 of unrecognized compensation expense related to non-vested stock options that are expected to be recognized over the next 2 months.

The following summarizes the status of options and warrants outstanding at December 31, 2015:

| Range of Exercise Prices | Shares | Weighted Average Remaining Life |
|---------------------------------|------------------|--|
| Options: | | |
| \$0.75 | 7,333 | 5.52 |
| \$2.63 | 250,481 | 9.81 |
| \$2.94 | 30,614 | 10.01 |
| \$3.10 | 59,681 | 9.50 |
| \$3.21 | 6,232 | 9.76 |
| \$3.45 | 7,245 | 9.25 |
| \$4.875 | 134 | 7.20 |
| \$5.25 | 2,031 | 6.69 |
| \$5.625 | 192,000 | 7.21 |
| \$5.925 | 23,206 | 7.22 |
| \$6.00 | 123,998 | 6.63 |
| \$6.50 | 3,845 | 9.01 |
| \$8.25 | 3,636 | 8.76 |
| \$9.9375 | 3,019 | 7.54 |
| \$10.50 | 3,238 | 7.54 |
| \$11.25 | 13,666 | 7.09 |
| \$12.75 | 67 | 7.36 |
| \$13.875 | 2,160 | 8.25 |
| \$71.25 | 40,261 | 8.19 |
| \$18.75 | 3,334 | 8.15 |
| \$20.25 | 4,940 | 8.01 |
| \$21.75 | 1,336 | 7.77 |
| \$23.85 | 1,260 | 7.75 |
| Total | 783,718 | |
| Warrants: | | |
| \$4.95 | 7,577,040 | 4.67 |
| \$6.00 | 102,857 | 2.20 |
| \$9.00 | 2,666 | 2.07 |
| \$9.75 | 63,227 | 3.59 |
| \$11.25 | 203,801 | 2.02 |
| \$12.375 | 71,257 | 3.61 |
| \$12.38 | 5,557 | 3.85 |
| \$13.50 | 4,444 | 2.47 |
| \$14.85 | 23,612 | 2.41 |
| \$20.25 | 1,481 | 3.13 |
| \$24.375 | 21,535 | 3.10 |
| Total | 8,077,477 | |

Stock options and warrants expire on various dates from June 2017 to December 2025.

On July 24, 2015, an amendment to the Certificate of Incorporation became effective, pursuant to which the authorized common stock was increased to 100,000,000 shares of common stock and the authorized preferred stock was increased to 20,000,000 shares.

Stock Options and Warrants Granted by the Company

The following table is the listing of stock options and warrants as of December 31, 2015 by year of grant:

Stock Options:

| Year | Shares | Price |
|-------|---------|----------------|
| 2011 | 11,666 | .75 |
| 2012 | 126,029 | 5.25 – 6.00 |
| 2013 | 232,756 | 4.875 – 23.85 |
| 2014 | 59,013 | 6.50 – 18.75 |
| 2015 | 354,253 | 2.63 – 3.45 |
| Total | 783,718 | \$.75 – 23.85 |

Warrants:

| Year | Shares | Price |
|-------|-----------|------------------|
| 2012 | 69,801 | 11.25 – 15.00 |
| 2013 | 267,579 | 6.00 – 14.85 |
| 2014 | 161,375 | 12.375 – 24.375 |
| 2015 | 7,578,722 | 4.95 |
| Total | 8,077,477 | \$ 4.95 – 24.375 |

NOTE 4 – SHORT-TERM NOTES PAYABLE

From July through September 2014, we entered into a series of securities purchase agreements pursuant to which we issued approximately \$1.8 million original principal amount (subsequently reduced to approximately \$1.6 million aggregate principal amount in accordance with their terms) of convertible promissory notes (the “2014 Convertible Notes”) and warrants exercisable for shares of our common stock for an aggregate purchase price of \$1,475,000. Of this amount, we issued to SOK Partners, LLC, an affiliate of the Company, \$122,196 original principal amount of the 2014 Convertible Notes and warrants exercisable for 5,431 shares of our common stock for an aggregate purchase price of \$100,000. In April and May 2015, we issued and sold to a private investor additional Convertible Notes in an aggregate original principal amount of \$275,000 for an aggregate purchase price of \$250,000, containing terms substantially similar to the 2014 Convertible Notes (the “2015 Convertible Notes” and, together with the 2014 Convertible Notes, the “Convertible Notes”). No warrants were issued with the 2015 Convertible Notes.

Under a provision in the existing agreements, upon effectiveness of a resale registration statement covering certain shares, on September 9, 2014, the principal amount of the notes was reduced by 11%, to \$1,603,260 and the number of Warrants was reduced by 11%, to 71,257 shares.

As of June 30, 2015, \$927,663 aggregate principal amount of Convertible Notes, plus accrued and unpaid interest thereto, have been converted into shares of our common stock and \$933,073 aggregate principal amount of Convertible Notes remained outstanding.

In connection with the Offering, the holders of the Convertible Notes agreed to not exercise their right to convert the Convertible Notes into shares of the Company’s common stock, in exchange for the Company’s agreement to redeem all of the outstanding Convertible Notes promptly following the consummation of the Offering at a redemption price equal to 140% of the principal amount, plus accrued and unpaid interest to the redemption date. On August 31, 2015, the closing date of the offering, the Company redeemed the remaining \$933,074 aggregate principal amount of Convertible Notes plus interest and a 40% redeemable premium, for a total payment of \$1,548,792. Of this amount, approximately \$167,031 was paid to its affiliates in redemption of their Convertible Notes. Each holder of the Convertible Notes agreed to the foregoing terms and entered into an Amendment to Senior Convertible Notes and Agreement with the Company. As of December 31, 2015 none of the Convertible Notes were outstanding.

NOTE 5 - LOSS PER SHARE

The following table presents the shares used in the basic and diluted loss per common share computations:

| | Year Ended December 31, | |
|--|----------------------------|------------------|
| | 2015 | 2014 |
| Numerator: | | |
| Net loss available in basic and diluted calculation | \$ (4,790,530) | \$ (6,833,568) |
| Denominator: | | |
| Weighted average common shares outstanding-basic | 3,880,828 | 2,990,471 |
| Effect of dilutive stock options, warrants and preferred stock (1) | - | - |
| Weighted average common shares outstanding-diluted | 3,880,828 | 2,990,471 |
| Loss per common share-basic and diluted | <u>\$ (1.23)</u> | <u>\$ (2.29)</u> |

(1) The number of shares underlying options and warrants outstanding as of December 31, 2015 and December 31, 2014 are 8,861,195 and 949,323, respectively. The number of shares underlying the preferred stock as of December 31, 2015 is 1,898,010. The effect of the shares that would be issued upon exercise of such options, warrants and preferred stock has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

NOTE 6- INCOME TAXES

The provision for income taxes consists of an amount for taxes currently payable and a provision for tax consequences deferred to future periods. Deferred income taxes are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

There is no income tax provision in the accompanying statements of operations due to the cumulative operating losses that indicate a 100% valuation allowance for the deferred tax assets and state income taxes is appropriate.

During September 2013, the Company experienced an "ownership change" as defined in Section 382 of the Internal Revenue Code which could potentially limit the ability to utilize the Company's net operating losses (NOLs). The general limitation rules allow the Company to utilize its NOLs subject to an annual limitation that is determined by multiplying the federal long-term tax-exempt rate by the Company's value immediately before the ownership change.

At December 31, 2014, the Company had approximately \$18.7 million of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2015, subject to the Section 382 limitation described above. The federal NOLs will expire beginning in 2022 if unused. The Company also had approximately \$12.4 million of gross NOLs to reduce future state taxable income at December 31, 2014, which will expire in years 2022 through 2034 if unused. The Company's net deferred tax assets, which include the NOLs, are subject to a full valuation allowance. At December 31, 2014, the federal and state valuation allowances were \$8.1 million and \$1.0 million, respectively.

At December 31, 2015, the Company had approximately \$24.7 million of gross NOLs to reduce future federal taxable income, the majority of which are expected to be available for use in 2016, subject to the Section 382 limitation described above. The federal NOLs will expire beginning in 2022 if unused. The Company also had approximately \$13.4 million of gross NOLs to reduce future state taxable income at December 31, 2015, which will expire in years 2022 through 2035 if unused. The Company's net deferred tax assets, which include the NOLs are subject to a full valuation allowance. At December 31, 2015, the federal and state valuation allowances were \$9.6 million and \$1.1 million, respectively.

The valuation allowance has been recorded due to the uncertainty of realization of the benefits associated with the net operating losses. Future events and changes in circumstances could cause this valuation allowance to change.

The components of deferred income taxes at December 31, 2015 and December 31, 2014 are as follows:

| | December 31, 2015 | December 31, 2014 |
|---------------------------|----------------------|----------------------|
| Deferred Tax Asset: | | |
| Net Operating Loss | \$ 10,338,000 | \$ 7,919,000 |
| Other | 359,000 | 1,150,000 |
| Total Deferred Tax Asset | 10,697,000 | 9,069,000 |
| Less Valuation Allowance | 10,697,000 | 9,069,000 |
| Net Deferred Income Taxes | <u>\$ —</u> | <u>\$ —</u> |

NOTE 7 – RENT OBLIGATION

The Company leases its principal office under a lease that can be cancelled after three years with proper notice per the lease and an amortized schedule of adjustments that will be due to the landlord. The lease extends five years and expires January 2018. In addition to rent, the Company pays real estate taxes and repairs and maintenance on the leased property. Rent expense was \$66,345 and \$64,753 for 2015 and 2014, respectively.

The Company's rent obligation for the next three years are as follows:

| | | |
|------|----|--------|
| 2016 | \$ | 38,000 |
| 2017 | \$ | 39,000 |
| 2018 | \$ | 3,000 |

NOTE 8 – LIABILITY FOR EQUITY-LINKED FINANCIAL INSTRUMENTS

The Company adopted ASC 815- Derivatives and Hedging ("ASC 815") on January 1, 2009. ASC 815 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature is indexed to the entity's own stock. It was effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, which was the Company's first quarter of 2009. Many of the warrants issued by the Company contain a strike price adjustment feature, which upon adoption of ASC 815, changed the classification (from equity to liability) and the related accounting for warrants with a \$479,910 estimated fair value of as of January 1, 2009. An adjustment was made to remove \$486,564 from paid-in capital (the cumulative values of the warrants on their grant dates), a positive adjustment of \$6,654 was made to accumulated deficit, representing the gain on valuation from the grant date to January 1, 2009, and \$479,910 was booked as a liability. The warrants issued in 2011 do not contain a strike price adjustment feature and, therefore, are not treated as a liability.

The January 1, 2009 valuation was computed using the Black-Scholes valuation model based upon a 2.5-year expected term, an expected volatility of 63%, an exercise price of \$34.50 per share, a stock price of \$26.25, a zero dividend rate and a 1.37% risk free interest rate. Subsequent to January 1, 2009 these warrants were re-valued at the end of each quarter and a gain or loss was recorded based upon their increase or decrease in value during the quarter. Likewise, new warrants that were issued during 2009 and 2010 were valued, using the Black- Scholes valuation model on their date of grant and an entry was made to reduce paid-in capital and increase the liability for equity-linked financial instruments. These warrants were also re-valued at the end of each quarter based upon their expected life, the stock price, the exercise price, assumed dividend rate, expected volatility and risk free interest rate. A significant reduction in the liability was realized in 2010 primarily due to a reduction from \$37.50 to \$16.50 per share in the underlying stock price. The Company realized a slight increase in the liability for existing warrants during the first quarter of 2012. In 2013 there was a significant decrease in the liability primarily due to current expirations and the amount of warrants reaching expiration in the near term. In 2014, all warrants expired and the liability was reduced to zero.

The inputs to the Black-Scholes model during 2009 through 2014 were as follows:

| | |
|-------------------------|-------------------|
| Stock price | \$3.75 to \$37.50 |
| Exercise price | \$.75 to \$24.38 |
| Expected life (years) | 2.0 to 6.5 |
| Expected volatility | 59% |
| Assumed dividend rate | -% |
| Risk-free interest rate | .13% to 2.97% |

The original valuations, annual gain (loss) and end of year valuations are shown below:

| | Initial Value | Annual Gain (Loss) | Value at 12/31/09 | 2010 Gain (Loss) | Value at 12/31/10 | 2011 Gain (Loss) | Value at 12/31/2011 | 2012 Gain (Loss) | Value at 12/31/2012 | 2013 Gain (Loss) | Value at 12/31/2013 | 2014 Gain (Loss) | Value at 12/31/2014 |
|--|---------------|--------------------|-------------------|------------------|-------------------|------------------|---------------------|------------------|---------------------|------------------|---------------------|------------------|---------------------|
| January 1, 2009 adoption | \$ 479,910 | \$ (390,368) | \$ 870,278 | \$ 868,772 | \$ 1,506 | \$ (88,290) | \$ 89,796 | \$ (21,856) | \$ 111,652 | \$100,053 | \$ 11,599 | \$ 11,599 | \$ - |
| Warrants issued in quarter ended 6/30/2009 | 169,854 | 20,847 | 149,007 | 147,403 | 1,604 | (4,689) | 6,293 | 6,293 | - | - | - | - | - |
| Warrants issued in quarter ended 9/30/2009 | 39,743 | (738) | 40,481 | 40,419 | 62 | (1,562) | 1,624 | 910 | 714 | 714 | - | - | - |
| Warrants is used in quarter ended 12/31/2009 | 12,698 | 617 | 12,081 | 12,053 | 28 | (724) | 752 | 415 | 337 | 337 | - | - | - |
| Subtotal | 702,205 | | 1,071,847 | | | | | | | | | | |
| Warrants issued in quarter ended 3/31/2010 | 25,553 | | | 25,014 | 539 | (5,570) | 6,109 | 3,701 | 2,408 | 2,408 | - | - | - |
| Warrants issued in quarter ended 6/30/2010 | 31,332 | | | 30,740 | 592 | (6,122) | 6,714 | 6,083 | 631 | 631 | - | - | - |
| Warrants issued in quarter ended 9/30/2010 | 31,506 | | | 20,891 | 10,615 | (44,160) | 54,775 | 1,338 | 53,437 | 53,437 | - | - | - |
| Total | \$ 790,596 | \$ (369,642) | \$ 1,071,847 | \$ 1,145,292 | \$ 14,946 | \$ (151,117) | \$ 166,063 | \$ (3,116) | \$ 169,179 | \$157,580 | \$ 11,599 | \$ 11,599 | \$ - |

NOTE 9 - RELATED PARTY TRANSACTIONS

The Audit Committee has the responsibility to review and approve all transactions to which a related party and the Company may be a party prior to their implementation, to assess whether such transactions meet applicable legal requirements. Rick Koenigsberger, a director, is a holder of membership units in SOK Partners.

In connection with the sale of the Series A Preferred Shares on February 4, 2014, Joshua Komberg, our President, Chief Executive Officer and Interim Chairman of the Board, was one of the purchasers. Mr. Komberg purchased 19,231 Series A Preferred Shares for a purchase price of \$25,000 and received warrants to purchase 52 shares of common stock.

SOK Partners, LLC (“SOK”), a 10% stockholder with Mr. Komberg and Dr. Samuel Herschkowitz as managing partners, invested in the July 2014 offering of convertible notes and warrants. In November 2014, the convertible noteholders agreed to convert certain balances of the convertible notes in connection with the public offering of the Existing Units, in consideration of the agreement to issue certain additional shares. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – History Financing – 2014 Sales of Convertible Notes and Warrants.” In connection with the Unit Offering in August 2015, all such convertible notes were redeemed at a redemption price of 140% of the principal amount thereof, plus accrued and unpaid interest. The Company paid approximately \$163,000 to SOK in redemption of its convertible note. In addition, Ricardo Koenigsberger, a former director who resigned on June 5, 2015, is a holder of membership units of SOK Partners.

In connection with the Unit Exchange that was consummated on August 31, 2015, 250 shares of Series A Convertible Stock held by Mr. Komberg were exchanged for 2,778 Exchange Units.

NOTE 10 – RETIREMENT SAVINGS PLANS

We have a pre-tax salary reduction/profit-sharing plan under the provisions of Section 401(k) of the Internal Revenue Code, which covers employees meeting certain eligibility requirements. In fiscal 2014, and again in 2015, we matched 100% of the employee’s contribution up to 4.0% of their earnings. The employer contribution was \$39,916 and \$37,730 in 2015 and 2014. There were no discretionary contributions to the plan in 2015 and 2014.

NOTE 11 – SUPPLEMENTAL CASH FLOW DATA

Cash payments for interest were \$246,620 and \$47,111 for the fiscal years ended December 31, 2015 and December 31, 2014, respectively.

NOTE 12 – SUBSEQUENT EVENTS

In January 2016 we commenced a registered offer (the “Exchange Offer”) to exchange, on a one-for-one basis, new units (the “New Units”) in exchange for the 1,895,010 outstanding units (the “Existing Units”) that were issued in the Offering and the Unit Exchange. Each New Unit, if issued, would have consisted of shares of common stock and certain warrants to purchase common stock. On March 2, 2016, we announced the termination of the Exchange Offer. None of the Existing Units were accepted for exchange in the Exchange Offer.

Schedule II

Valuation and Qualifying Accounts

(None)

**OFFER TO EXCHANGE SERIES B WARRANTS
FOR SERIES A WARRANTS**

**THE EXCHANGE OFFER WILL EXPIRE AT MIDNIGHT, EASTERN TIME,
ON APRIL 21, 2016, UNLESS EXTENDED
(SUCH DATE AND TIME, AS THE SAME MAY BE EXTENDED,
THE “EXPIRATION DATE”).**



PROSPECTUS

Dealer Manager

SOURCE CAPITAL GROUP, INC.

The date of this prospectus is _____, 2016.
